
From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/18/2020 6:26:08 PM
To: [b6] [b6]
BCC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: [EXTERNAL] Hever and COVID

Great, thanks!

From: [b6] [b6]
Sent: Saturday, April 18, 2020 2:15 PM
To: Collins, Francis (NIH/OD) [E] <[b6]>
Subject: Re: [EXTERNAL] Hever and COVID

Francis

The draft agenda has you to present ACTIV at HEVER call , invitations will come shortly for a HEVER call.

I will introduce the need for a Covid group where federal agencies of NIH-FDA-EMEA-BARDA -EU - Academia (eg Wellcome-IMI) come together w Pharma -Biotech

I think it's important to try to have everyone come together for ACTIV and ensure that ACTIV has productive links to EU etc

Best
[b6]

Sent from my iPhone

On Apr 18, 2020, at 13:56, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi [b6]

I understand that you are pulling together a Hever discussion on COVID-19 therapeutic and vaccine efforts. That sounds like a great idea, as there are a lot of meritorious activities underway and some confusion about how they overlap or synergize. If there would be any use for me to join part of a Hever call to say something about the plans for the ACTIV public-partnership, I'd be glad to do so. On the other hand, you are already pretty well briefed about this, so this may not be necessary. This coming Wednesday April 22 at 10 AM, there will be a virtual meeting of the senior leadership (including you) that initiated ACTIV on April 3, where a summary of progress will be reported.

COLL0000010649

Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/18/2020 8:26:21 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] Hever and COVID

Oh wow, I didn't know about David's Dad – I am truly sorry to hear this.

I would think that the slides being prepared for the April 22 check in with the "Friday group" ought to be a pretty good set for what I would need for Hever. We have a prep call about that at 11:30 am on Monday, let's see what that looks like.

FYI and not for broader distribution, the diagnostics issues have become red hot. One consequence is that Rick Bright, the head of BARDA, now reports 50% to me. You can't make this stuff up.

Francis

From: Freire, Maria (FNIH) [T] <[REDACTED]> b6
Sent: Saturday, April 18, 2020 3:07 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: [EXTERNAL] Hever and COVID

Francis will you need slides for the Hever presentation? Please let me know.

David's dad is COVID-19 positive. He is about 96 and in a nursing home in CT. So I am trying to lighten his load as much as possible, deflecting and reassigning as needed.

If we can get a head start on these and work with someone on your side to get them to you, it would be great. M.

From: "Collins, Francis (NIH/OD) [E]" [REDACTED] b6
Date: Saturday, April 18, 2020 at 1:26:09 PM
To: [REDACTED] b6 " [REDACTED] b6
Subject: RE: [EXTERNAL] Hever and COVID

Great, thanks!

From: [REDACTED] b6 [REDACTED] b6
Sent: Saturday, April 18, 2020 2:15 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Re: [EXTERNAL] Hever and COVID

Francis

The draft agenda has you to present ACTIV at HEVER call , invitations will come shortly for a HEVER call.

I will introduce the need for a Covid group where federal agencies of NIH-FDA-EMEA-BARDA -EU - Academia (eg Wellcome-IMI) come together w Pharma -Biotech

COLL0000010660

I think it's important to try to have everyone come together for ACTIV and ensure that ACTIV has productive links to EU etc

Best
b6

Sent from my iPhone

On Apr 18, 2020, at 13:56, Collins, Francis (NIH/OD) [E] < b6 > wrote:

Hi b6

I understand that you are pulling together a Hever discussion on COVID-19 therapeutic and vaccine efforts. That sounds like a great idea, as there are a lot of meritorious activities underway and some confusion about how they overlap or synergize. If there would be any use for me to join part of a Hever call to say something about the plans for the ACTIV public-partnership, I'd be glad to do so. On the other hand, you are already pretty well briefed about this, so this may not be necessary. This coming Wednesday April 22 at 10 AM, there will be a virtual meeting of the senior leadership (including you) that initiated ACTIV on April 3, where a summary of progress will be reported.

Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/21/2020 7:55:27 PM
To: [b6] [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: [b6] [b6]
Subject: RE: ACTIV

Understood, no problem, glad you can be there for the second half.

Francis

-----Original Message-----

From: [b6] [b6]
Sent: Tuesday, April 21, 2020 3:50 PM
To: Collins, Francis (NIH/OD) [E] <[b6]> [b6] Wholley, David (FNIH) [T] <[b6]>
Cc: [b6] [b6]
Subject: ACTIV

Hi

I look forward to the ACTIV meetings .
Tomorrow I will call in w 30 min delayed to our 10-11 am meeting as I am speaking at a corporate web cast that ends 1030

Sorry for that inconvenience
[b6]

Sent from my iPhone

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 2:43:38 PM
To: [REDACTED] [REDACTED]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: [EXTERNAL] ACTIV Executive Committee

Wonderfull

Besides Paul and myself, I'm aiming for you and William Pao from industry, Tony Fauci and Gary Gibbons from NIH, and Janet Woodcock from FDA. Not all have said yes so far, but I think I've got a good chance of 100% acceptance.

Best, Francis

From: [REDACTED] <[REDACTED]>
Sent: Tuesday, May 5, 2020 10:41 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Cc: Wholley, David (FNIH) [T] <[REDACTED]>
Subject: Re: [EXTERNAL] ACTIV Executive Committee

Francis

It's always a pleasure to work w you and Paul on initiatives to shape biomedicine and certainly urgent for the pandemic .

I think this is a good move you propose as it's currently somewhat unclear where governance is happening and a smaller team of senior experienced leaders makes this feasible .

I am Happy to join the executive committee leadership team given the importance of this Covid task .

How many will be in the team , if it's too many it's hard to discuss and be effective but of course you want some diverse views also

Best

[REDACTED]

Sent from my iPhone

On May 5, 2020, at 10:09, Collins, Francis (NIH/OD) [E] [REDACTED] wrote:

Hi [REDACTED]

Many thanks for all of your thoughtful input to ACTIV as we move this partnership forward at record speed. I am looking forward to hearing the working group reports on Wednesday.

A task that we haven't addressed yet is to make the Leadership Group a bit more organized. As you know better than almost anyone, for the Accelerating Medicines Partnership (AMP) projects we benefited from an Executive Committee, co-chaired by you and me, and populated with a few other senior members from both sectors. For ACTIV, Paul Stoffels has agreed to serve as co-chair with me, but

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I am hoping you might be willing to serve as an Executive Committee member. The duties will not be onerous -- FNIH staff will take care of all the logistics and planning, the main responsibility would be to look over draft agendas and help lead the Leadership Group discussions.

Let me know if you would be willing to do this – it would be great to have your expertise again, especially at this critical moment.

Best, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/12/2020 10:15:48 AM
To: Disbrow, Gary (OS/ASPR/BARDA) [b6]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Disbrow, Gary (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62a151e39ab942d88a813b449f9f6ccb-Gary.Disbro]; Blatner, Gretta (OS/ASPR/BARDA) [b6 Johnson, Robert (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=feb0b05457404e2f8b88af78e9ac4dd9-Robert.John]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Getting together

Hi Gary,

Great. I'll ask Gretchen and Ayanna to work through Gretta to set this up. I'd like to include Larry Tabak, Cliff Lane, and David Wholley. This will be about therapeutics and vaccines, we may need a separate discussion in a few days about diagnostics, but that would involve a separate cast of characters from NIH.

Best, Francis

From: Disbrow, Gary (OS/ASPR/BARDA) < b6
Sent: Tuesday, May 12, 2020 4:15 AM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: Tabak, Lawrence (NIH/OD) [E] < b6 Wood, Gretchen (NIH/OD) [E] < b6
McManus, Ayanna (NIH/OD) [E] < b6 Disbrow, Gary (OS/ASPR/BARDA)
< b6 Blatner, Gretta (OS/ASPR/BARDA) < b6
Subject: RE: Getting together

Francis,

Apologies for the delayed response. Gretta can assist with setting this up. I would like to include Robert Johnson from BARDA. He is currently our Incident Manager for the BARDA response.

Gary

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary

Director, Medical Countermeasure Programs

Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR

Department of Health and Human Services

330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201

Office: b6

Mobile: b6

Fax: 202-205-0873

COLL0000010943

email: [REDACTED] b6

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From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Monday, May 11, 2020 5:20 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <[REDACTED] b6>
Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 ; Wood, Gretchen (NIH/OD) [E] [REDACTED] b6 ;
McManus, Ayanna (NIH/OD) [E] [REDACTED] b6
Subject: Getting together

Hi Gary,

I'd like to get together (virtually of course) this week to survey where we are with coordination of NIH and BARDA efforts on therapeutics and vaccines. Having us all linked up through ACTIV has been really helpful, but I'd like to be sure that we have achieved seamless integration of ACTIV recommendations and BARDA decision-making on contract support for clinical trials and manufacturing scale up. I will want to include Larry Tabak and possibly one or two other NIHers.

Who could Gretchen and Ayanna work with to find a time for this discussion?

Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 1:13:27 AM
To: Woodcock, Janet [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV leadership

Understood – but can you nominate someone from FDA to take your spot in the Clinical Trials Working Group? We need continuity there!

Best, Francis

From: Woodcock, Janet <b6>
Sent: Monday, May 4, 2020 3:23 PM
To: Collins, Francis (NIH/OD) [E] <b6>
Cc: Wholley, David (FNIH) [T] <b6>
Subject: RE: ACTIV leadership

Ok. I will have to drop off the working groups then. Jw

From: Collins, Francis (NIH/OD) [E] <b6>
Date: May 4, 2020 at 2:23:47 PM EDT
To: Marks, Peter <b6>, Woodcock, Janet <b6>
Cc: Wholley, David N (NIH) <b6>
Subject: RE: ACTIV leadership

Thanks to you both – Janet, you're it!!

Francis

From: Marks, Peter <b6>
Sent: Monday, May 4, 2020 12:51 PM
To: Woodcock, Janet (FDA/CDER) <b6>; Collins, Francis (NIH/OD) [E] <b6>
Cc: Wholley, David (FNIH) [T] <b6>
Subject: RE: ACTIV leadership

Dear Francis and Janet,

I am absolutely fine with having Janet take this on. No hurt feelings whatsoever!

Thank you Janet.

Best Regards,
Peter

From: Woodcock, Janet <b6>
Sent: Monday, May 4, 2020 12:43 PM

COLL0000011011

To: Collins, Francis S (NIH) [REDACTED] b6 ; Marks, Peter [REDACTED] b6
Cc: Wholley, David N (NIH) [REDACTED] b6
Subject: RE: ACTIV leadership

I don't think that would work. I'm happy to have Peter do it, I am going to be very busy in my new role. Maybe you can invite me in my new role?? jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Monday, May 4, 2020 12:34 PM
To: Woodcock, Janet [REDACTED] b6 ; Marks, Peter [REDACTED] b6
Cc: Wholley, David N (NIH) [REDACTED] b6
Subject: ACTIV leadership

Hi Janet and Peter,

We need to form an Executive Committee of the ACTIV partnership, to drive the agenda forward. Following the example of AMP, co-chairs from industry and government seem like a good idea – and so I have asked Paul Stoffels to serve as co-chair with me. He has agreed.

But for other members of the Ex Comm, I would like to have FDA represented. I doubt that Steve Hahn has time for this, and I can't very well ask one of you without asking the other – but how about I ask Amy Abernethy? Would that make sense from your perspective?

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 12:40:48 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: (b) (5)

War room tomorrow is fine, thanks

From: Wholley, David (FNIH) [T] < (b) (5) >
Sent: Thursday, May 14, 2020 8:31 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) >
Subject: RE: (b) (5)

We ran out of time on today's call before I could give you and the war room group my upload of my call with Janet, which took place just before (and slightly overlapped the BARDA call last evening). We can speak on the war room tomorrow or happy to chat before then if you need to.

From: Collins, Francis (NIH/OD) [E] < (b) (5) >
Sent: Thursday, May 14, 2020 8:22 PM
To: Wholley, David (FNIH) [T] < (b) (5) >
Subject: FW: (b) (5)

Hi David,

See note below from Janet. (b) (5) (b) (5)

(b) (5)

FC

From: Woodcock, Janet < (b) (5) >
Sent: Thursday, May 14, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) >
Subject: (b) (5)

(b) (5)

I will be there tomorrow, despite my staunch resistance, so maybe I'll see you at the announcement. jw

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 12:41:09 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Meeting with Moncef

I'd like to be the bearer of this one.

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, May 14, 2020 8:36 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: Meeting with Moncef

Absolutely we can share. Let me check to make sure we have the best and latest. OK if I send to you, Janet, and Peter simultaneously or do you want to be the bearer?

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, May 14, 2020 5:39 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6
Subject: FW: Meeting with Moncef

See Janet's question. I can send the slides that show the steps, what the criteria were, and what the results were (confidential of course) – but is there anything more granular that can be shared?

FC

From: Woodcock, Janet [REDACTED] b6
Sent: Thursday, May 14, 2020 5:09 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6; Marks, Peter (FDA/CBER) [REDACTED] b6
Subject: RE: Meeting with Moncef

I've put a hold on my calendar. Also Moncef asked if he could see the proceeds or deliberations about ranking the therapeutics. Is there a document someone can forward them about how they came up with their lead repurposed candidates? jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, May 14, 2020 4:57 PM
To: Marks, Peter [REDACTED] b6; Woodcock, Janet [REDACTED] b6
Subject: Meeting with Moncef

Hi Peter and Janet,

I understand you are meeting with Moncef tonight to begin the process of getting him up to speed on the wide array of COVID-19 activities. He's also accepted an invitation to meet virtually with the ACTIV "War Room" folks (including Larry Tabak, David Wholley, Cliff Lane, Chris Austin, Jim Anderson, Maria Freire, Ashley Parker, and me), Tony Fauci, and John Mascola on Monday from 8:30 – 9:30 am. If there is any way that you could join that WebEx meeting, at least for part of the time, that would be terrific.

Just let me know if that might work for you.

Best, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/14/2020 9:39:43 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Meeting with Moncef

Peter will join

From: Marks, Peter <[REDACTED] b6>
Sent: Thursday, May 14, 2020 5:01 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6> Woodcock, Janet (FDA/CDER) <[REDACTED] b6>
Subject: Re: Meeting with Moncef

Dear Francis,

Thanks so much. That will work perfectly for me.

Best Regards,
Peter

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Date: May 14, 2020 at 4:57:02 PM EDT
To: Marks, Peter [REDACTED] b6 >, Woodcock, Janet [REDACTED] b6
Subject: Meeting with Moncef

Hi Peter and Janet,

I understand you are meeting with Moncef tonight to begin the process of getting him up to speed on the wide array of COVID-19 activities. He's also accepted an invitation to meet virtually with the ACTIV "War Room" folks (including Larry Tabak, David Wholley, Cliff Lane, Chris Austin, Jim Anderson, Maria Freire, Ashley Parker, and me), Tony Fauci, and John Mascola on Monday from 8:30 – 9:30 am. If there is any way that you could join that WebEx meeting, at least for part of the time, that would be terrific.

Just let me know if that might work for you.

Best, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/15/2020 12:22:16 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: (b) (5)

Hi David,

See note below from Janet. (b) (5) (b) (5)

(b) (5)

FC

From: Woodcock, Janet < (b) (5) >
Sent: Thursday, May 14, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) >
Subject: (b) (5)

(b) (5)

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/15/2020 8:12:52 AM
To: b6 [b6]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: [EXTERNAL] Progress of the partnership

Hey there b6

I totally agree with connecting as much as possible with the Europeans and Brits. We've reached out to Jeremy Farrar and Patrick Vallance and built a strong connection with the UK COVID therapeutics effort. And John Young of Roche (our Preclinical WG co-chair) is involved in the IMI preclinical effort, which involves a call for compounds to submit to large-scale screening at the Rega Institute at the University of Leuven in Belgium.

Best, Francis

From: b6 < b6>
Sent: Tuesday, April 14, 2020 3:27 PM
To: Collins, Francis (NIH/OD) [E] < b6>
Cc: Freire, Maria (FNIH) [T] < b6> Wholley, David (FNIH) [T] < b6>
Subject: Re: [EXTERNAL] Progress of the partnership

Hi Francis
Thanks for the note .

Happy to support this exciting alliance initiatives in appropriate interviews w quality journals . I have been quite active in media to underline the role of science to find a long lasting medical solution urgently to stop the pandemic

Let's use HEVER to see if we can make this ACTIV as the preeminent Covid science alliance and pull in additional participation.

For HEVER it is often initiatives that go beyond USA that engages the entire group including EMEA . How can we link in EU to this ? I noted you did invite EU groups in previous meetings , how do we extend it into the future ? EMEA, IMI or Wellcome Trust?

Best
b6

Sent from my iPhone

On Apr 14, 2020, at 15:07, Collins, Francis (NIH/OD) [E] b6 wrote:

Hey b6

The public-private partnership on COVID-19, now dubbed ACTIV (for Accelerating COVID-19 Therapeutic Interventions and Vaccines) is off to a quick and action-oriented start – all four working groups have now met and are already hard at work, ably supported by FNIH. I reattach the output from the

inaugural meeting just 11 days ago, and the rosters of the working groups. Thanks for providing excellent participants from Pfizer.

The press has got wind of this and is interested in writing something about how all the sectors are getting together to enhance progress. I think these will be very positive stories. Is it OK if I send an occasional reporter your way for a comment?

I also understand that you are convening a Hever group in the next week or so to discuss ways to optimize the COVID-19 response. If there are Hever members that would like to join ACTIV and haven't already done so, we would welcome their participation. I hear that some senior industry scientists are feeling overburdened with a great number of these planning groups springing up. I think at this point that ACTIV may have the best chance to achieve real progress, given the wide involvement of industry, NIH, BARDA, and FDA – as well as skillful and muscular staff leadership from David Wholley and the whole FNIH team, supplemented by additional experienced staff from Deloitte.

Many thanks for all you are doing for the cause. I sincerely hope your wife is doing much better by now.

Francis

<FNIH Covid 19 meeting April 03 2020 notes.docx>
<Covid Working Group Rosters - MASTER.pdf>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 4/14/2020 7:31:04 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: FW: [EXTERNAL] Progress of the partnership

See below, Dolsten is happy to be a press contact for ACTIV.

FC

From: b6 <b6>
Sent: Tuesday, April 14, 2020 3:27 PM
To: Collins, Francis (NIH/OD) [E] <b6>
Cc: Freire, Maria (FNIH) [T] <b6> Wholley, David (FNIH) [T] <b6>
Subject: Re: [EXTERNAL] Progress of the partnership

Hi Francis
Thanks for the note .

Happy to support this exciting alliance initiatives in appropriate interviews w quality journals . I have been quite active in media to underline the role of science to find a long lasting medical solution urgently to stop the pandemic

Let's use HEVER to see if we can make this ACTIV as the preeminent Covid science alliance and pull in additional participation.

For HEVER it is often initiatives that go beyond USA that engages the entire group including EMEA . How can we link in EU to this ? I noted you did invite EU groups in previous meetings , how do we extend it into the future ? EMEA, IMI or Wellcome Trust?

Best

b6

Sent from my iPhone

On Apr 14, 2020, at 15:07, Collins, Francis (NIH/OD) [E] b6 wrote:

Hey b6

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Francis

<FNIH Covid 19 meeting April 03 2020 notes.docx>

<Covid Working Group Rosters - MASTER.pdf>

Sent: 8/27/2020 6:53:21 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholley]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: SUPER URGENT: Complete list of POC diagnostics needed for urgent COVID clinical trials
Attachments: POC Diagnostic Request for CP Trials 080620.xlsx

Hi Ashley,

OASH has come through with the Abbott ID Now machines and tests. As you can see from the table below, they will meet the need presented in your summary table (attached).

From: Giroir, Brett (HHS/OASH) <[REDACTED]> b6
Sent: Tuesday, August 11, 2020 10:37 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Roach, Jessica (HHS/OASH) <[REDACTED]> b6
Subject: FW: Complete list of POC diagnostics needed for urgent COVID clinical trials
Importance: High

This is what we can do for Abbott ID NOW.
We are leaving nothing in the SNS until we finish this.

CAN YOU SEND SHIPPING ADDRESSES BY NOON TOMORROW? We can only ship from Abbott 1x per week.
Jess Roach can coordinate with your team

Brett P. Giroir, M.D.
ADM, U.S. Public Health Service
Assistant Secretary for Health (ASH) (HHS)
U.S. Representative, Executive Board, WHO (DOS)

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: [REDACTED] b6

From: Roach, Jessica (HHS/OASH) [REDACTED] b6
Sent: Tuesday, August 11, 2020 6:52 PM
To: Giroir, Brett (HHS/OASH) [REDACTED] b6
Cc: Beckham, Tammy (HHS/OASH) <[REDACTED]> b6 Bosch, LCDR Miguel (OS/IOS)

b6 >

Subject: RE: Complete list of POC diagnostics needed for urgent COVID clinical trials

Good evening ADM Giroir,

Below please find the proposed delivery schedule of Abbott ID NOW instruments and tests to meet NIH's request, as well as required information that we need from NIH by noon tomorrow in order to meet this schedule.

We reserved (b) (4)
(b) (4)

Please let us know if you need anything else.

Thanks,

Jess

(b) (4)

Required information from NIH – due by NOON, 12 August.

- Shipping address and on-site point-of-contact (email and phone number) for each location.
- The number of instruments and test kits that should be sent to each location, delineated by week in accordance with the proposed shipping schedule. Note that tests come in kits of 24.

From: Giroir, Brett (HHS/OASH) < b6 >

Sent: Saturday, August 8, 2020 4:03 PM

To: Collins, Francis (NIH/OD) [E] < b6 >

Cc: Parker, Ashley (NIH/NCI) [F] < b6 >; Beckham, Tammy (HHS/OASH) < b6 >;

Roach, Jessica (HHS/OASH) < b6 >; Giroir, Brett (HHS/OASH) < b6 >

Subject: RE: Complete list of POC diagnostics needed for urgent COVID clinical trials

Thanks Francis for the consolidated list.

We are not going to be able to meet this delivery deadline, but are working on a plan to do what we can - including by decreasing clinical supplies to many states.

This is obviously a critical need and we recognize that; and I think we can get you where you need to be on a reasonable schedule.

We will have a plan for you in the first couple days of this week.

In the future, as much heads up as possible would be appreciated!

All of us are very concerned that ERs will use this just for clinical diagnostics, and not for trial enrollment. So we are counting on you to be ruthless in looking at tests versus enrollment!

COLL0000011406

Sent: 12/29/2020 3:54:01 PM
To: Slaoui, Moncef [REDACTED] b6
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]
Subject: RE: Mutation tracking proposal

Hi Moncef,

Thanks for your quick response. The number I mentioned over the phone was for a scaled-down one-year effort, but it's hard to imagine this being a need that goes away after December 2021. The current proposal is more ambitious than what we discussed, designed to cover 120 total variants/year for three years. A 40 variant proposal (more like what we discussed by phone) would be [REDACTED] (b) (5) Years 2 and 3 are based on the efforts from year 1, so would also scale with variants. I can send a revised proposal for that scale, if that would be helpful.

CDC is a major contributor to the proposal and there is a [REDACTED] (b) (5) in the first year to enhance their sequencing efforts. CDC will need to be the main driver of the emerging surveillance effort and a contributor to testing. This proposal is meant to augment and accelerate the process across USG and include industry involvement.

Let me know what I can to help with this consideration.

Francis

From: Slaoui, Moncef <[REDACTED] b6>
Sent: Tuesday, December 29, 2020 9:04 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: Mutation tracking proposal

Hi Francis

Thank you for following up .

We will look into this of course, but two points I would like to share

- 1- The budget [REDACTED] (b) (5)
[REDACTED] (b) (5)

- 2-

Thank you
Moncef

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Tuesday, December 29, 2020 8:08 AM
To: Slaoui, Moncef [REDACTED] b6 >
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6; Anderson, James (NIH/OD) [E] [REDACTED] b6
Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6>; Wholley, David (FNIH) [T] [REDACTED] b6; Freire, Maria (FNIH) [T] [REDACTED] b6; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6; Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6; Erbeling, Emily (NIH/NIAID) [E] [REDACTED] b6; Marston, Hilary (NIH/NIAID) [E] [REDACTED] b6; Woodcock, Janet (FDA/CDER) <[REDACTED] b6>; Hepburn, Matt (HHS/IOS)

Subject: Mutation tracking proposal

Hi Moncef,

As discussed with you briefly by phone last week, the ACTIV Preclinical Working Group has been hard at work shaping a program that would track newly arising mutations in SARS-CoV-2 and gather information quickly about their significance. Up until now, this has been a bit of a scattershot effort, with a lot of work going on in separate public and private organizations, but no agreement for immediate sharing of the data in a publicly accessible database. The recent emergence of variants in the UK and South Africa has added further urgency to this effort, though this ACTIV plan began before those gained wide public attention.

Attached is a five-step proposal about how to organize a much more effective approach, with significant input from industry, NIH, CDC, and FDA. The three-year budget comes to (b) (5)

I would appreciate your thoughts about how best to proceed with this request for support.

I'd be glad to discuss this further by phone if that would be helpful. Joe Menetski of the Foundation for NIH has been the primary curator of the plan, and would also be glad to provide further details about the components of the plan.

Best, Francis

Sent: 12/29/2020 12:58:39 PM
To: Slaoui, Moncef [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94a42f399e84dfbbcc4d6650ac6d6ef-Moncef.Slao]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Marston, Hilary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab30660917b942ffba9ae95d631116f3-marstonhd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Hepburn, Matt (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2f43022aeb34b44a905a094631f56ff-Matt.Hepbur]
Subject: Mutation tracking proposal
Attachments: ACTIV_ Preclinical_ Emerging Sequence Surveillance Proposal_F6.docx

Hi Moncef,

As discussed with you briefly by phone last week, the ACTIV Preclinical Working Group has been hard at work shaping a program that would track newly arising mutations in SARS-CoV-2 and gather information quickly about their significance. Up until now, this has been a bit of a scattershot effort, with a lot of work going on in separate public and private organizations, but no agreement for immediate sharing of the data in a publicly accessible database. The recent emergence of variants in the UK and South Africa has added further urgency to this effort, though this ACTIV plan began before those gained wide public attention.

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I would appreciate your thoughts about how best to proceed with this request for support.

I'd be glad to discuss this further by phone if that would be helpful. Joe Menetski of the Foundation for NIH has been the primary curator of the plan, and would also be glad to provide further details about the components of the plan.

Best, Francis

Sent: 8/1/2020 10:15:57 PM
To: b6 b6
CC: b6 Ledgerwood, Julie (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dc9f31ded594eff8ac506d2c4103c15-ledgerwood]; Richardson-Heron, Dara [b6 Sowards, Judy Jae-Hee [b6 Harnaga, Ed [b6
Subject: RE: Diversity in the Vaccine Clinical Trials

Thanks for your follow up note, b6

One more thought about DSMBs – could you be comfortable with their sharing data about safety signals? That would seem to be in public's best interest.

From: b6 b6
Sent: Friday, July 31, 2020 2:13 PM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: b6 Ledgerwood, Julie (NIH/NIAID) [E] < b6 b6
< b6 b6 < b6 b6
< b6
Subject: RE: Diversity in the Vaccine Clinical Trials

Dear Francis,

It was very nice speaking with you earlier this week. Our Chief Patient officer, Dara Richardson-Heron, who you know well, and our Head of Clinical Trial Experience, Judy Sowards, are reviewing the options you laid out below and will be reaching out to Jim and Julie directly to discuss.

I very much look forward to continuing this dialogue and exploring the ways we can work together to help ensure people from all demographics, who may have interest in participating in COVID-19 clinical trials are aware of, educated about and have access to them.

Sincerely,

b6

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Wednesday, July 29, 2020 8:36 AM
To: b6 b6
Cc: Wood, Gretchen (NIH/OD) [E] < b6 McManus, Ayanna (NIH/OD) [E] < b6
Subject: RE: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Yes, let's get on a call to discuss. Gretchen and/or Ayanna can help find a good time.

Best, Francis

From: [REDACTED] b6 <[REDACTED] b6>
Sent: Monday, July 27, 2020 3:20 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6; Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] b6>; Wholley, David (FNIH) [T] [REDACTED] b6; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6
Subject: Re: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Hi Francis

Thanks for the response .

We appreciate the opportunity to access the NIH data bases and I will have someone reaching out to your contact persons below .

For some of the general best practice aspects of special populations and diversity inclusions , maybe the ACTIV NIH Vaccine and Clinical sub-groups can serve as useful venues as we are participating in those .

I am fine to discuss additional aspects you brought up , such as DSMB processes in a 1:1 phone call with you

Best
[REDACTED] b6

Sent from my iPhone

On Jul 26, 2020, at 20:53, Collins, Francis (NIH/OD) [E] [REDACTED] b6 > wrote:

Hi [REDACTED] b6

Thanks for your note, and my sincere apologies for the slow response. I've consulted with the folks who have set up the www.coronaviruspreventionnetwork.org in order to register those interested in vaccine trials. There is a general sense that [REDACTED] (b) (4)

(b) (4)

To come back to your original question, NIAID is happy to discuss ways of (b) (4), (b) (5)

Points of contact would be Jim Kublin (b6 and Julie Ledgerwood b6

Best, Francis

From: b6 b6 >
Sent: Thursday, July 23, 2020 8:57 AM
To: Collins, Francis (NIH/OD) [E] < b6 >
Subject: Diversity in the Vaccine Clinical Trials

Dear Francis,

I hope this note finds you and your family well. I'm writing to ask your assistance in ensuring people who want to participate in COVID-19 clinical trials are able to easily access the information they need, and in efforts to support diversity in the vaccine clinical trials.

We know that speed in the recruitment of diverse clinical trial participants will be critical to moving *all* COVID-19 vaccine programs forward. I know you are keenly aware that educating the public about clinical trials, and making it as simple as possible to find a trial and participate, is essential to doing that.

In the quest for a vaccine for COVID-19, we are all in it together. In that spirit of partnership and collaboration, I respectfully request you consider including Pfizer's Covid-19 clinical trial, and the clinical trials of other non-U.S. government-sponsored COVID-19 studies, in the Covid-19 Prevention Network (CoVPN) registry.

Pfizer and other COVID-19 vaccine developers need help to ensure that participants in our trials reflect the disproportionate rates of infection in black and brown communities. Many NIH programs are rich resources and potential recruitment partners to reach diverse individuals who have already expressed an interest in research, including NCATS, CTSAs and the All of Us Research Program. If Pfizer and other study teams have the opportunity to benefit from access to these groups, this may help us to significantly diversify the participants in COVID-19 vaccine studies. Of course, we would be willing to provide any required information to ensure the success of these partnerships.

As the leader of the nation's medical research agency, we look to you for guidance on the advancement of all efforts to discover and develop vaccines to combat the virus that continues to take many lives in the U.S. and around the world. Thank you for your consideration, and I hope to hear from you soon.

Sincerely,

b6

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/13/2021 2:12:20 AM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Thanks — Kevin appreciates you dedicating an entire session and requested to invite COL Teyhen as well? She is assisting with the transition activities and can help with any follow ups.

Thanks,
Ashley

On Apr 12, 2021, at 8:45 PM, Tabak, Lawrence (NIH/OD) [E] [b6] wrote:

Ok - thanks

From: Francis Collins <[b6]>
Date: Monday, April 12, 2021 at 8:44 PM
To: "Parker, Ashley (NIH/OD) [E]" <[b6]>, "Wholley, David (FNIH) [T]" <[b6]>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[b6]>, "Freire, Maria (FNIH) [T]" <[b6]>
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Yes, if Janet is joining we should certainly extend that courtesy.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 12, 2021 6:59 PM
To: Wholley, David (FNIH) [T] [b6] >; Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Sounds good to me – Francis, are you OK with giving Kevin and Janet the full 30 mins? I will send them the dial-in information once I have the green light.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Monday, April 12, 2021 6:50 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Collins, Francis (NIH/OD) [E]
[REDACTED] b6
Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6; Freire, Maria (FNIH) [T]
[REDACTED] b6
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

You know, [REDACTED] (b) (5)
[REDACTED] (b) (5)
[REDACTED]

David

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Monday, April 12, 2021 5:51 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E]
[REDACTED] b6; Freire, Maria (FNIH) [T] [REDACTED] b6
Subject: Re: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Great, thanks. Kevin sent a follow up note — Janet will also join the war room call on Wednesday and they will also use this time to discuss the USG Tx Preparedness Infrastructure Proposal.

Hopefully 15 mins will be enough time — seem OK?

I will circulate all materials once in hand.

Thanks,
Ashley

On Apr 12, 2021, at 4:43 PM, Collins, Francis (NIH/OD) [E] [REDACTED] b6 > wrote:

This looks like a good list. And we can be generous and allow him 15 minutes.

FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, April 12, 2021 11:54 AM
To: Wholley, David (FNIH) [T] [REDACTED] b6; Collins, Francis (NIH/OD) [E]
[REDACTED] b6
Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Freire, Maria (FNIH) [T]
[REDACTED] b6
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Agree — please see addition below. Does this work?

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Monday, April 12, 2021 11:51 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>; Collins, Francis (NIH/OD) [E]
[REDACTED] b6

Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED] >; Freire, Maria (FNIH) [T]
< [REDACTED] b6 [REDACTED]

Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Great job, Ashley. [REDACTED] (b) (5)

[REDACTED] (b) (5)

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]

Sent: Monday, April 12, 2021 11:46 AM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] >

Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Wholley, David (FNIH) [T]
[REDACTED] b6 [REDACTED]

Subject: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Hi Francis,

Below is a draft note for me to send to Kevin with questions that I captured from the war room. Larry – I've included the question about the connection with other USG Lessons as I understand there has been interest to keep this effort separate due to limited focus on Tx's. Cc'ing David as well in case I've missed anything from the broader USG Tx discussions.

I standby for any edits before sending to Kevin and please let me know if I need to amend the time.

Thanks,
Ashley

Hi Kevin,

Thank you again for offering to speak with the war room about the USG Tx activities. We typically meet via teleconference for 30 minutes and it would be great to have you join us this Wednesday, 4/14 at 8am for the first 10-12 mins (roughly **5-min high level overview** of the USG Tx Operational structure/workstreams ~ **5 slides** and **5-7 mins for questions/discussion**). Our time will be limited but yes, please feel free to include any pertinent information on the proposal for the infrastructure bill that was drafted recently.

To provide more context and clarity for the discussion, the war room has seen the large slide sets for the USG Tx Lessons Learned, USG Tx Strategy, and possibly other slides that have been shared through some of the other USG Tx workstreams and I agree the group would benefit from understanding the USG Tx organizational structure with all of the various components of the workstreams/activities in an effort to fully capture the USG Tx activities and overarching goals. In addition, below are a few questions that may arise and help bring clarity.

- What is the overall organizational structure of the USG Tx including the (who) leading agencies/participants, (what) workstreams, etc.?
- What are the goals of the various workstreams?
- What is the timeline to complete the goals? What is the future of USG Tx?
- How are these workstreams/activities linked with other USG agencies Lesson's Learned activities?

- Is NIH well represented in the current USG Tx plans/workstreams? How can we best serve in these efforts?

If you could please send me the read ahead materials by COB tomorrow to share with the group and I will follow up with the dial-in information for Wednesday's call.

Thank you,
Ashley

From: Bugin, Kevin <[REDACTED]> b6
Sent: Monday, April 12, 2021 10:57 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: War Room this week

Hi Ashley,

I hope you had a nice weekend!

I wanted to check and see if I was still going to be able to join your War Room this Wed. If so, I can talk through the Operation structure and long-term operational plans, as planned, but can also talk through a proposal for the infrastructure bill that was drafted recently. I believe this was shared with Francis and Larry. In case it was not, the proposal was around investing in community-based clinical trial sites/networks—a key insight from our lessons learned work.

Kevin

Sent: 2/26/2021 6:58:32 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]
Subject: FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
Attachments: Draft BIRD Proceedings 25-02-2021 v 1.4.pdf

FYI.

From: Woodcock, Janet <[REDACTED]> b6
Sent: Friday, February 26, 2021 1:12 PM
To: Kessler, David (HHS/IOS) <[REDACTED]> b6 Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> b6 Bugin, Kevin (FDA/CDER) <[REDACTED]> b6 Teyhen, Deydre (HHS/IOS) <[REDACTED]> b6 Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Subject: FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

Another good reason to get ACTIV 6 up and running. Solid evidence still lacking. jw

From: Tess Lawrie <[REDACTED]> b6
Sent: Friday, February 26, 2021 10:59 AM
To: Abernethy, Amy <[REDACTED]> b6 Anderson, Erika <[REDACTED]> b6 Yiannas, Frank <[REDACTED]> b6 Tyler, James <[REDACTED]> b6 Tierney, Julia <[REDACTED]> b6 Hinton, Denise <[REDACTED]> b6 Raza, Mark <[REDACTED]> b6 Abdoo, Mark <[REDACTED]> b6 Araujo, Richard <[REDACTED]> b6 McMeekin, Judith <[REDACTED]> b6 Rebello, Heidi <[REDACTED]> b6 Roth, Lauren <[REDACTED]> b6 Tantillo, Andrew <[REDACTED]> b6 Vasisht, Kaveeta <[REDACTED]> b6 Felberbaum, Michael <[REDACTED]> b6 Mair, Michael <Michael.Mair@fda.hhs.gov>; Mettler, Erik <[REDACTED]> b6 Miller, Elizabeth <[REDACTED]> b6 Rogers, Michael <[REDACTED]> b6 Cavazzoni, Patrizia <[REDACTED]> b6 Marks, Peter <Peter.M[REDACTED]> b6 Mayne, Susan <[REDACTED]> b6 Pazdur, Richard <[REDACTED]> b6 Slikker, William <[REDACTED]> b6 Solomon, Steven M <[REDACTED]> b6 Stein, Peter <[REDACTED]> b6 Woodcock, Janet <[REDACTED]> b6
Cc: claire Mock-Muñoz de Luna <[REDACTED]> b6 Ketan Gajjar <[REDACTED]> b6 Andy Bryant <[REDACTED]> b6 Tony Tham <[REDACTED]> b6 Scott Mitchell <[REDACTED]> b6 Tina

COLL0000012242

Subject: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

The BIRD recommendation on covid-19 prevention and treatment

The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the 'very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

Sent: 3/22/2021 3:40:53 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=504f61b222f148348e5f1a8c1fc6aa07-DBJ0]
CC: Dugan, Vivien (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dd967831ed54d6f8a6bb355efd5224d-lny1]; Galloway, Summer (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4b7bab0c866407daf1300fac6b527c9-nmd3]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: question about viral isolates chosen for sequencing

Hi Nancy,

New York might be a factor, but the main driver was the argument for vigilance for whatever comes next that might be worse than B.1.526 or B.1.351. And if you were going to go looking for that, sequencing the virus in vaccine breakthroughs would seem to be a good idea.

The ACTIV Leadership Team also raised questions about viral isolates from underserved groups. I've asked Joni Rutter to follow up with you and Dan about that.

Best, Francis

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) < b6 >
Sent: Monday, March 22, 2021 7:32 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < b6 > Collins, Francis (NIH/OD) [E] < b6 >
Cc: Dugan, Vivien (CDC/DDID/NCIRD/ID) < b6 > Galloway, Summer (CDC/DDID/NCIRD/ID) < b6 >
Erbeling, Emily (NIH/NIAID) [E] < b6 >
Subject: RE: question about viral isolates chosen for sequencing

Just to add a bit. We have been in touch with Emily around our breakthrough cases, including sending the one-pager on breakthrough investigations. David Kessler has already reached out to CDC, OWS, ASPR and NIH about serology for breakthrough cases and, I think, had asked Robert Johnson to organize a call about that. Is this conversation coming up again because of NYC as there seem to be multiple conversations related to that. If so, our state and local team is working with them on their investigations.

Nancy

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) b6
Sent: Sunday, March 21, 2021 10:11 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) b6 ; Dugan, Vivien (CDC/DDID/NCIRD/ID) b6

Galloway, Summer (CDC/DDID/NCIRD/ID) < [REDACTED] b6

Subject: RE: question about viral isolates chosen for sequencing

Francis:

Thanks. Regarding sequencing of variants, yes, priority will be given to any specimen/virus available. I have cc'd Vivien Dugan who can address the efforts, and the challenges in getting available specimen after the initial testing is done.

There is a specific effort on facilitating evaluation of these cases. Nancy is cc'd and can respond and connect folks from the Vaccine Task Force that are working on studies and surveillance to address what you have identified. I have attached a slide deck from a NSC briefing the SIG gave on Friday which addresses this in the vaccine section around slide 20. There is a table with the various activities. Let us know if this answers the question and happy to work with Nancy on follow ups.

Thanks

Dan.

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Sent: Sunday, March 21, 2021 9:15 PM

To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < [REDACTED] b6

Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [REDACTED] b6

Subject: question about viral isolates chosen for sequencing

Hi Dan,

A question came up at the ACTIV leadership team meeting last week that I wasn't able to answer. In CDC's surveillance of viral genome sequencing, is special priority being placed on isolates from individuals who developed COVID-19 after vaccination (the "breakthroughs")? Those samples would of course be of special interest and concern, since they might represent new and more resistant variants that we would want to know about. I know some of the states seem to be prioritizing these samples, but is that something that CDC is directing across the country?

Thanks, Francis

Sent: 4/11/2021 9:28:04 PM
To: Bradner, James [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; [b6]
Subject: RE: [EXTERNAL] BGTC

Hey Jay,

Thanks for your note. That is wonderful news about BGTC! I'd love to talk with you more about this. Would you have any time on Monday?

Best, Francis

From: Bradner, James < b6>
Sent: Friday, March 26, 2021 1:20 PM
To: b6 < b6>
Cc: Wholley, David (FNIH) [T] < b6> Collins, Francis (NIH/OD) [E] < b6>
Subject: Re: [EXTERNAL] BGTC

thank you, b6 for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated the "avexis" R&D into novartis. this will surely be a good move to accelerate the portfolio, also wrt efficiencies and data/scholarship. as such, the discovery and early clinical development of all gene therapies will now be led by my leadership team at NIBR. so i am getting up to speed on partnerships and collaborations.

could i put upon an NIH leader to meet and discuss the status of BGTC, and introduce the priorities, strategies and resources we have (in particular data)? as below, there are real champions from avexis who now migrate to NIBR, and i am hopeful they will remain as closely connected to this rising opportunity to work together as before.

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b

**BLACK
LIVES
MATTER**



From: b6 b6
Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner < b6>
Cc: David Wholley < b6> "Collins Francis [E]" < b6>
Subject: Re: [EXTERNAL] BGTC

Jay

COLL0000012263

I and (I assume\$ Frances are thrilled that you want to join the GTx consortia

I ask David Wholley provide you w details

On the anti virals , we expect soon to be in P2/3 studies for both IV and Oral as we have generated quite some favorable P1b data already

Lessons learned on biomarkers cross studies would fit well for ACTIV sharing as best practice

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James <[REDACTED]> wrote:

thanks, [REDACTED]

(b) (4)

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] | @jaybradner

From: b6 [b6]
Sent: 1/16/2021 7:54:16 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Good plan

We look forward to the feedback on the IV drug and we are open to add the oral in the next step pending positive ACTIV feedback

Best
b6

Sent from my iPhone

On Jan 16, 2021, at 13:57, Collins, Francis (NIH/OD) [E] < b6 > wrote:

Good question. For at least the next several months, I'd like to stick with the ACTIV model, as it has made it possible to move things forward more efficiently. The dedication of the Working Groups, the access to FNIH program management, and the close connections with FDA help a lot here.

Francis

From: b6 b6
Sent: Saturday, January 16, 2021 11:44 AM
To: Collins, Francis (NIH/OD) [E] < b6 >
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Francis

One thing that came to my mind, do you regard ACTIV as the main potential way to collaborate between NIH-Pfizer on the IV and oral SARSCov2 protease inhibitor (PI) drugs that will be going into phase two studies now (iv) or soon (oral)?

Do you foresee any alternative potential structure government - company that would be more of a closer bilateral collaboration, similarly as you did w MODERNA in the vaccine? I assume the new administrator may also use BARDA like pathways

Just thought it would be good to consider which alternative may be best suited given the dire pandemic and this is the first PI.

What's your thoughts ?

b6

Sent from my iPhone

COLL0000012286

On Jan 16, 2021, at 09:44, Collins, Francis (NIH/OD) [E] [b6] > wrote:

Hey [b6]

This sounds really interesting! I assume Phase 1 data looks good for any safety signal. Is the preclinical data available somewhere? I'd bet you are also working on an oral or SQ alternative?

Best, Francis

From: [b6] [b6]
Sent: Friday, January 15, 2021 1:10 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Fwd: Pfizer ACTIV submission

Hope you will find this compelling
It's the first in class highly potent Sarcov2 protease inhibitors . We have human phase 1 data concluded .

Would be nice to see if we can work w NIH-ACTIV on this one

[b6]

Sent from my iPhone

Begin forwarded message:

From: [b6] [b6]
Date: January 15, 2021 at 12:52:06 EST
To: "Adam, Stacey (FNIH) [T]" [b6]
Cc: "[b6] [b6], [b6]
[b6], [b6]"
Subject: Pfizer ACTIV submission

Dear Stacey

I hope all is well. I'd like to give you the heads up that we are submitting PF-07304814, our IV protease inhibitor to the ACTIV portal today. We also have the IB that can be provided if required under the CDA that was signed this week.

Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best
Liesa

Annaliesa S Anderson Ph.D. FAAM

Chief Scientific Officer Bacterial Vaccines

Chief Scientific Officer Hospital Business Unit

Pfizer Vaccine Research and Development, Bldg 222, Rm 3184

401 N Middletown Road | Pearl River | NY 10965 | USA |

Tel: (b6) | Mobile: b6 | Fax: (845) 474-5150

b6

Hi Liesa,

Thank you for letting us know. If your team is willing since we have the CDA in place, it would be great to have the IB to include with your portal submission for the review group. Would that be possible?

Either way, we will be in touch post our review of the agent to let you know the ACTIV review team's feedback on the agent.

Thank you again for your interest in having it considered for our trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: [REDACTED] b6

Sent: Friday, January 15, 2021 12:52 PM

To: Adam, Stacey (FNIH) [T] <[REDACTED] b6>

Cc: [REDACTED] b6 <[REDACTED] b6> [REDACTED] b6 [REDACTED] b6
[REDACTED] b6 [REDACTED] b6

Subject: Pfizer ACTIV submission

Dear Stacey

I hope all is well. I'd like to give you the heads up that we are submitting PF-07304814, our IV protease inhibitor to the ACTIV portal today. We also have the IB that can be provided if required under the CDA that was signed this week.

Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best

[REDACTED] b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/17/2021 4:56:33 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] RE: Pfizer ACTIV submission

Great, thanks.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Sunday, January 17, 2021 11:06 AM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] RE: Pfizer ACTIV submission

Yes, please – antivirals are absolutely critical, and [REDACTED] (b) (4), (b) (5)

I have also shared this information with Tony Fauci.

FC

From: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Sent: Sunday, January 17, 2021 10:45 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6; Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] RE: Pfizer ACTIV submission

Thank you, Francis,

I appreciate you making us aware of this exchange. We will work to get this agent queued up for review as quickly as we can with our ACTIV review team.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Saturday, January 16, 2021 4:27 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6; Adam, Stacey (FNIH) [T] <[REDACTED]> b6; Freire, Maria (FNIH) [T] <[REDACTED]> b6

COLL0000012290

b6

Subject: FW: [EXTERNAL] RE: Pfizer ACTIV submission

From: b6

b6

Sent: Saturday, January 16, 2021 2:54 PM

To: Collins, Francis (NIH/OD) [E] b6

Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Good plan

We look forward to the feedback on the IV drug and we are open to add the oral in the next step pending positive ACTIV feedback

Best

b6

Sent from my iPhone

On Jan 16, 2021, at 13:57, Collins, Francis (NIH/OD) [E] b6 wrote:

Good question. For at least the next several months, I'd like to stick with the ACTIV model, as it has made it possible to move things forward more efficiently. The dedication of the Working Groups, the access to FNIH program management, and the close connections with FDA help a lot here.

Francis

From: b b6

Sent: Saturday, January 16, 2021 11:44 AM

To: Collins, Francis (NIH/OD) [E] < b6

Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Francis

One thing that came to my mind, do you regard ACTIV as the main potential way to collaborate between NIH-Pfizer on the IV and oral SARSCov2 protease inhibitor (PI) drugs that will be going into phase two studies now (iv) or soon (oral)?

Do you foresee any alternative potential structure government - company that would be more of a closer bilateral collaboration, similarly as you did w MODERNA in the vaccine? I assume the new administrator may also use BARDA like pathways

Just thought it would be good to consider which alternative may be best suited given the dire pandemic and this is the first PI.

What's your thoughts ?

COLL0000012290

b6

Sent from my iPhone

On Jan 16, 2021, at 09:44, Collins, Francis (NIH/OD) [E] b6 > wrote:

Hey Mikael,

This sounds really interesting! I assume Phase 1 data looks good for any safety signal. Is the preclinical data available somewhere? I'd bet you are also working on an oral or SQ alternative?

Best, Francis

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To: Collins, Francis (NIH/OD) [E] b6
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Would be nice to see if we can work w NIH-ACTIV on this one

b6

Sent from my iPhone

Begin forwarded message:

From: b6 b6
Date: January 15, 2021 at 12:52:06 EST
To: "Adam, Stacey (FNIH) [T]" < b6
Cc: b6 b6 , b6
b6 , b6
Subject: Pfizer ACTIV submission

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Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best

b6

COLL0000012290

b6



From: Bugin, Kevin [REDACTED] b6
Sent: 1/16/2021 9:48:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Shapiro, Neil (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a13c20d004cb413b9484d6343b5f3fa6-shapironk]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV program to address SARS-CoV-2 variants

Hi Francis,

Hope you are having a good weekend. Thank you for the contacts! I will put them in touch with HHS/ASFR regarding some of the questions they have on timing of funding obligations and the logistics transfers.

Kevin

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Saturday, January 16, 2021 10:43 AM
To: Bugin, Kevin <[REDACTED] b6>
Cc: Woodcock, Janet <[REDACTED] b6> Menetski, Joseph M (NIH) <[REDACTED] b6> Tabak, Lawrence A (NIH) <[REDACTED] b6> Shapiro, Neil K (NIH) <[REDACTED] b6> Wholley, David N (NIH) <[REDACTED] b6>
Subject: RE: ACTIV program to address SARS-CoV-2 variants

Hi Kevin,

That would be Neil Shapiro, though he may need a quick description of the project (I'm reattaching it here). I'm also looping in Larry Tabak, Joe Menetski, and David Wholley in case they are needed to help. I'm really glad to hear HHS finance is engaged.

Francis

From: Bugin, Kevin [REDACTED] b6
Sent: Friday, January 15, 2021 4:57 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Woodcock, Janet (FDA/CDER) [REDACTED] b6
Subject: RE: ACTIV program to address SARS-CoV-2 variants

Francis,

Who from NIH budget office could I work with to sort through all of this and how it would be provided? I'm starting to get question from HHS finance folks (good sign), but I'll need details on obligation dates, vehicles for transfers, contracts, etc. Can you connect me to a NIH budget guru to work with on this?

Kevin

COLL0000012291

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, January 14, 2021 11:25 PM
To: Woodcock, Janet <[b6]>
Cc: Bugin, Kevin [b6]; Menetski, Joseph M (NIH) [b6]; Wholley, David N (NIH) [b6]; Freire, Maria C (NIH) [b6]
Subject: ACTIV program to address SARS-CoV-2 variants

Hi Janet and Kevin,

See attached for the ACTIV proposal that captures all of the components for calendar year 2021. The budget request is (b) (5). I also attach a draft slide (still being reviewed, not for further distribution) that illustrates the relationship between the ACTIV program and the USG-only effort (now called SIG instead of SCIRAM). That reflects the discussions that have gone on for the last couple of days with Joe Menetski, Dan Jernigan, and John Mascola. Let me know what else I can do to help support this ACTIV proposal – I agree with you that this is of great urgency and needs to start right away.

Many thanks, Francis

From: Woodcock, Janet [b6]
Sent: Thursday, January 14, 2021 4:57 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Bugin, Kevin (FDA/CDER) [b6]
Subject: RE: variant effort

Good, I will need a \$\$ figure that rolls it all up ASAP if we are to get funding from us. jw

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, January 14, 2021 4:31 PM
To: Woodcock, Janet [b6]
Subject: RE: variant effort

Hi Janet,

That's being actively worked on right now – SCIRAM can be the USG-only connection between agencies to be sure we are coordinating across HHS, and can deal with priority decisions where industry might have a conflict of interest. I'm expecting the merger that Joe Menetski (ACTIV) and Dan Jernigan (SCIRAM) are leading will produce a result in the next 18 hours.

Francis

From: Woodcock, Janet <[b6]>
Sent: Thursday, January 14, 2021 4:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: variant effort

How do we talk about the SCIRAM effort and its relationship to what you want to do with ACTIV? I think I can get some funding but will need to explain. jw

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/18/2021 2:38:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

I may be out of email contact until evening, fyi. If anything truly urgent please call cell [REDACTED] b6 Thanks

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Monday, January 18, 2021 7:23 AM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Cc: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Thanks for this background. We'll definitely need to keep our eyes open.

FC

From: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Sent: Sunday, January 17, 2021 9:21 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Cc: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Francis,
Stacey is not near her computer just now but texted me. FYI Stacey had already reached out to Adrian Hernandez at Janet's request—Janet just did not include that in her email to Josie. Also, we will try to get you the answer on flvoxamine but as I said in war room our plan was to check back with Eric Lenze on his trial to see if he can move his trial forward before we try to place it in an ACTIV trial. Stacey did speak to Eric, and he told her recruitment is picking up. Finally strictly an editorial comment on my part but I have been part of trying to work with [REDACTED] (b) (5)

[REDACTED]
[REDACTED] David

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Sunday, January 17, 2021 7:14 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED] b6 [REDACTED]> Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Can you answer the question about placebo?

From: Woodcock, Janet <[REDACTED] b6 [REDACTED]>
Sent: Sunday, January 17, 2021 5:42 PM

COLL0000012292

To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6

Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

I don't know about fluvoxamine placebo. Would hope could randomize 1:1:1 but regimens may be different. Jw

From: Collins, Francis (NIH/OD) [E] < [REDACTED] b6

Date: January 17, 2021 at 4:26:55 PM EST

To: Woodcock, Janet < [REDACTED] b6

Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

Hi Janet,

I just spoke with Josie Briggs about PCORnet possibly taking this on. Though she has some PTSD from the failed PCORnet project on HCQ, she can see the potential here, and will discuss it with Nakela. She says they may have some funds remaining from the HCQ outpatient study, since that was terminated early – but probably that won't be enough if they are going to test both ivermectin and fluvoxamine. I have heard there is an ivermectin placebo ready to go – is that also available for fluvoxamine?

She gets it that there is some urgency here.

Francis

From: Woodcock, Janet < [REDACTED] b6

Sent: Sunday, January 17, 2021 11:35 AM

To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6

Subject: FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

PCORNET would be the best bet I think. I may have trouble working on this starting WED, but is important to get done. Just don't know the vehicle, would need some sort of contract. But I think they would be the fastest. jw

From: Adrian Hernandez, M.D. < [REDACTED] b6

Sent: Sunday, January 17, 2021 10:53 AM

To: Woodcock, Janet < [REDACTED] b6

Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

Janet

Yes, could potentially take on depending on agent/requirements.

Let me know how best to learn more. Mobile is below if helpful.

Adrian

[REDACTED] b6

From: Janet Woodcock <[REDACTED]> b6
Date: Sunday, January 17, 2021 at 9:51 AM
To: "Adrian Hernandez, M.D." <[REDACTED]> b6
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

I wanted to know if PCORNET could potentially take on a large, pragmatic, potentially government-funded trial of relatively safe repurposed agents in outpatients with COVID-19. jw

From: Adrian Hernandez, M.D. <[REDACTED]> b6
Sent: Saturday, January 16, 2021 5:16 PM
To: [REDACTED] b6
Cc: Woodcock, Janet <[REDACTED]> b6
Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Hi

Just let me know what's needed

Adrian

[REDACTED] b6

On Jan 16, 2021, at 5:06 PM, Robert Califf <[REDACTED]> b6 wrote:

his email address is in the header--he'll respond.

[REDACTED] b6

rmc

On Sat, Jan 16, 2021 at 2:03 PM Woodcock, Janet <[REDACTED]> b6 wrote:

Contact info? Tx jw

From: Robert Califf <[REDACTED]> b6
Sent: Saturday, January 16, 2021 4:57 PM
To: Woodcock, Janet <Janet.[REDACTED]> b6; Adrian Hernandez, M.D. <[REDACTED]> b6
Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Adrian Hernandez is PI--

rmc

On Sat, Jan 16, 2021 at 1:55 PM Woodcock, Janet <[REDACTED]> b6 wrote:

Yeah, but they match ACTIV 3. We should have more clinical data soon.

Need contact point for PCORNET not PCORI> jw

From: Robert Califf <[REDACTED] b6>

Sent: Saturday, January 16, 2021 12:12 PM

To: Woodcock, Janet <[REDACTED] b6>

Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

yes; i think it would help it if you put public pressure on the org to deliver

will send more info

do you know when we'll have more readout from Lilly or Regeneron? Clinicians are skeptical and the Recovery conv plasma results aren't helping.

rmc

On Sat, Jan 16, 2021 at 8:48 AM Woodcock, Janet <[REDACTED] b6> wrote:

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/17/2021 3:45:16 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] RE: Pfizer ACTIV submission

Thank you, Francis,

I appreciate you making us aware of this exchange. We will work to get this agent queued up for review as quickly as we can with our ACTIV review team.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Saturday, January 16, 2021 4:27 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6> Adam, Stacey (FNIH) [T] <[REDACTED] b6> Freire, Maria (FNIH) [T] <[REDACTED] b6>
Subject: FW: [EXTERNAL] RE: Pfizer ACTIV submission

From: [REDACTED] b6 [REDACTED] b6
Sent: Saturday, January 16, 2021 2:54 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Good plan
We look forward to the feedback on the IV drug and we are open to add the oral in the next step pending positive ACTIV feedback

Rest
[REDACTED] b6

Sent from my iPhone

On Jan 16, 2021, at 13:57, Collins, Francis (NIH/OD) [E] <[REDACTED] b6> wrote:

COLL0000012295

Good question. For at least the next several months, I'd like to stick with the ACTIV model, as it has made it possible to move things forward more efficiently. The dedication of the Working Groups, the access to FNIH program management, and the close connections with FDA help a lot here.

Francis

From: [REDACTED] b6 [REDACTED] b6
Sent: Saturday, January 16, 2021 11:44 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission

Francis

One thing that came to my mind, do you regard ACTIV as the main potential way to collaborate between NIH-Pfizer on the IV and oral SARS-CoV2 protease inhibitor (PI) drugs that will be going into phase two studies now (iv) or soon (oral)?

Do you foresee any alternative potential structure government - company that would be more of a closer bilateral collaboration, similarly as you did w MODERNA in the vaccine? I assume the new administrator may also use BARDA like pathways

Just thought it would be good to consider which alternative may be best suited given the dire pandemic and this is the first PI.

What's your thoughts?

[REDACTED] b6

Sent from my iPhone

On Jan 16, 2021, at 09:44, Collins, Francis (NIH/OD) [E] [REDACTED] b6 > wrote:

Hey [REDACTED] b6

This sounds really interesting! I assume Phase 1 data looks good for any safety signal. Is the preclinical data available somewhere? I'd bet you are also working on an oral or SQ alternative?

Best, Francis

From: [REDACTED] b6 [REDACTED] b6
Sent: Friday, January 15, 2021 1:10 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Fwd: Pfizer ACTIV submission

Hope you will find this compelling

It's the first in class highly potent Sarcov2 protease inhibitors . We have human phase 1 data concluded .

Would be nice to see if we can work w NIH-ACTIV on this one

b6

Sent from my iPhone

Begin forwarded message:

From: b6 b6
Date: January 15, 2021 at 12:52:06 EST
To: "Adam, Stacey (FNIH) [T]" b6
Cc: b6 b6 , b6
b6 , b6
Subject: Pfizer ACTIV submission

Dear Stacey

I hope all is well. I'd like to give you the heads up that we are submitting PF-07304814, our IV protease inhibitor to the ACTIV portal today. We also have the IB that can be provided if required under the CDA that was signed this week.

Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best

b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/17/2021 5:09:01 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] RE: Message
Attachments: 2021-01-14_ACTIV_Leadership_Team_and_Executive_Committee_Meeting_Summary_vF.docx; 01.14 ACTIV EC and Leadership Team Meeting 20210113_FINAL.pptx

Hi Francis,
This came in late last night and I reviewed it this morning. I am about to send it out to all the meeting participants but if you want to send an additional copy to b6 so it is at the top of his inbox it is attached, along with a copy of the slides presented on Thursday. David

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Saturday, January 16, 2021 12:47 PM
To: Wholley, David (FNIH) [T] <b6>
Subject: FW: [EXTERNAL] RE: Message

How soon will there be a summary of the LT meeting? Is there something I can share with b6 in the next day or so?

FC

-----Original Message-----

From: b6 b6
Sent: Friday, January 15, 2021 9:13 PM
To: Collins, Francis (NIH/OD) [E] <b6>
Subject: Re: [EXTERNAL] RE: Message

Hi Francis

I share the view that understanding the immune response and viral sequences in breakthrough infections after vaccination and in previously infected patients would be an important path for assessing immune correlates.

I am sorry I couldn't make the ACTIV meeting but I was in J.P. Morgan investor meetings with our CEO those days .

How did the meeting go ?

Certainly we will look for ways to share data in this important matter .

It will also be critical to discuss and define parameters that may influence when it's time to consider a potential future shift of the vaccine sequences due to accumulation of possible viral mutations . While this may be way into the future as we are dealing w a polyclonal response , it's a good preparedness to have in mind

Potentially some of the existing mAbs may soon be influenced by the numerous mutations close to their epitopes .

Talk to you soon

b6

Sent from my iPhone

> On Jan 11, 2021, at 15:09, Collins, Francis (NIH/OD) [E] <b6> wrote:

> Hey b6

> The topic of immune correlates of protection against COVID-19 illness is on the agenda for the ACTIV Leadership Team on Thursday. I think ACTIV is exactly the right group to work on assembling all of the information possible on immune correlates. Breakthrough patients who get infected despite vaccination are crucial to unravel this -- so having Pfizer's team included would be critical for the kind of inferences that the world is waiting for.

>

> Any chance you can join on Thursday (I heard you might have a conflict)? Can we get your help in sharing Pfizer's data?

>

> Francis

>

> -----Original Message-----

> From: b6 <b6>

> Sent: Sunday, January 10, 2021 11:28 AM

> To: Collins, Francis (NIH/OD) [E] <b6>

> Subject: Re: [EXTERNAL] RE: Message

>

> Hi Francis

>

> Thanks for the response

> Indeed a dark DC week

>

> While extending dose cross ages based on immune bridge is somewhat straightforward, the reduction of dose is more complex .

>

> It's not just the quantity of the immune response (in vitro ab Neuts assay) to consider but also the quality and nature of the various immune parameters Ki.

>

> What in vitro assay readouts correlates w in vivo vaccine efficacy? How do we move from guesstimates to stronger quantitative predictions while ensuring we provide the demonstrated >90% vaccine efficacy to participants . Science will get there but needs to be rigorous

>

> I welcome as always dialogue around this at the appropriate time point

>

> Best

> b6

>

>

>

> Sent from my iPhone

>

>> On Jan 9, 2021, at 21:57, Collins, Francis (NIH/OD) [E] b6 wrote:

>> Hi b6

>>

>> Apologies for the slow response. Your message fell through the cracks in what has been a terribly disheartening week here in DC -- and for our whole country.

>>

>> I couldn't access the Seeking Alpha article, there's a firewall. But I think I know what it probably said. From John Mascola, there is no surprising plan here. (b) (4)

(b) (4)

>> Best, Francis

>>

>>

>>

>> -----Original Message-----

>> From: b6 b6

>> Sent: Tuesday, January 5, 2021 3:17 PM

>> To: Collins, Francis (NIH/OD) [E] <b6>

>> Subject: Message

>>

>> Francis

>>

>> We discussed the half dose issue recently

>>

>> Is this a follow up info of relevance to what we discussed as it mentions NIH?

>>

>> Is there a public available plan how you can do dose selection w a two month the study?

>>

>> Moderna and NIH to study the effects of halving the COVID-19 shot - NYT

>> <https://seekingalpha.com/news/3649017-moderna-and-nih-to-study-effects-of-halving-covidminus-19-shot-nyt>

>>

>>

>> Sent from my iPhone

From: Bugin, Kevin [REDACTED] b6
Sent: 1/15/2021 1:30:03 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV program to address SARS-CoV-2 variants

Thanks, Francis. I will work with Janet to get this into the process for funding ASAP from OWS.

I do have one question as someone not familiar with all of the discussions to date—is there a need to involve anyone from FDA in the interagency group?

Kevin

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Thursday, January 14, 2021 11:25 PM
To: Woodcock, Janet <[REDACTED] b6>
Cc: Bugin, Kevin <[REDACTED] b6> Menetski, Joseph M (NIH) <[REDACTED] b6> Wholley, David N (NIH) <[REDACTED] b6> Freire, Maria C (NIH) <[REDACTED] b6>
Subject: ACTIV program to address SARS-CoV-2 variants

Hi Janet and Kevin,

See attached for the ACTIV proposal that captures all of the components for calendar year 2021. The budget request is (b) (5) . I also attach a draft slide (still being reviewed, not for further distribution) that illustrates the relationship between the ACTIV program and the USG-only effort (now called SIG instead of SCIRAM). That reflects the discussions that have gone on for the last couple of days with Joe Menetski, Dan Jernigan, and John Mascola. Let me know what else I can do to help support this ACTIV proposal – I agree with you that this is of great urgency and needs to start right away.

Many thanks, Francis

From: Woodcock, Janet [REDACTED] b6
Sent: Thursday, January 14, 2021 4:57 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Cc: Bugin, Kevin (FDA/CDER) [REDACTED] b6
Subject: RE: variant effort

Good, I will need a \$\$ figure that rolls it all up ASAP if we are to get funding from us. jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, January 14, 2021 4:31 PM

COLL0000012516

To: Woodcock, Janet [REDACTED] b6

Subject: RE: variant effort

Hi Janet,

That's being actively worked on right now – SCIRAM can be the USG-only connection between agencies to be sure we are coordinating across HHS, and can deal with priority decisions where industry might have a conflict of interest. I'm expecting the merger that Joe Menetski (ACTIV) and Dan Jernigan (SCIRAM) are leading will produce a result in the next 18 hours.

Francis

From: Woodcock, Janet [REDACTED] b6

Sent: Thursday, January 14, 2021 4:12 PM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Subject: variant effort

How do we talk about the SCIRAM effort and its relationship to what you want to do with ACTIV? I think I can get some funding but will need to explain. jw

From: Shapiro, Neil (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A13C20D004CB413B9484D6343B5F3FA6-SHAPIRONK]
Sent: 2/23/2021 5:30:36 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Summary of ACTIV progress
Flag: Follow up

I spoke to Lester Cash. Do you have time to discuss?

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, February 17, 2021 2:52 PM
To: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6
Shapiro, Neil (NIH/OD) [E] <[REDACTED]> b6 Hallett, Adrienne (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6
Subject: FW: Summary of ACTIV progress

FYI

From: Kessler, David (HHS/IOS) [REDACTED] b6
Sent: Wednesday, February 17, 2021 1:53 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: Summary of ACTIV progress

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Can I request that I get a little bit of time to do that and they will bring in Neil etc
And then we can all gather
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Sent: Wednesday, February 17, 2021 1:44 PM
To: Kessler, David (HHS/IOS) <[REDACTED]> b6
Subject: Summary of ACTIV progress

Hi David,

Thanks for the call this morning.

(b) (5)

(b) (5)

COLL0000012538

Perhaps the progress and promise of therapeutics hasn't been as well described as it should have been, given the focus on vaccines. I've hit you with budget information, but not the science – which is actually a lot more fun. So here are a few items you might enjoy looking over in a spare (ha!) moment. My NIH Director's blog yesterday was an up-to-date summary (see <https://directorsblog.nih.gov/2021/02/16/activ-update-making-major-strides-in-covid-19-therapeutic-development/>) and pointed to a tabulation of all of the current trials (see <https://www.nih.gov/activ/nih-funded-activ/activ-associated-clinical-trials>). We also just had an ACTIV Leadership Team meeting today, and I attach the confidential ppt file from that if you want to browse through the topics we discussed.

I stand ready to do whatever is necessary to clarify this situation – just say the word!

Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 2/23/2021 5:31:06 PM
To: Shapiro, Neil (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a13c20d004cb413b9484d6343b5f3fa6-shapironk]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: Summary of ACTIV progress
Flag: Follow up

Sure – just let me know when.

From: "Shapiro, Neil (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Date: Tuesday, February 23, 2021 at 12:30 PM
To: Francis Collins <[REDACTED] b6 [REDACTED]> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: RE: Summary of ACTIV progress

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To: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] b6 [REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Shapiro, Neil (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Hallett, Adrienne (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 [REDACTED]>
Subject: FW: Summary of ACTIV progress

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Sent: 2/23/2021 5:39:30 PM
To: Shapiro, Neil (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a13c20d004cb413b9484d6343b5f3fa6-shapironk]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Please call me [REDACTED] b6

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[REDACTED] (b) (5)

COLL0000012540

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From: Woodcock, Janet [REDACTED] b6
Sent: 1/15/2021 2:34:51 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV program to address SARS-CoV-2 variants
Flag: Follow up

WE will put this through ASAP. Critical issue. jw

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Thursday, January 14, 2021 11:25 PM
To: Woodcock, Janet <[REDACTED] b6>
Cc: Bugin, Kevin <[REDACTED] b6>; Menetski, Joseph M (NIH) <[REDACTED] b6>; Wholley, David N (NIH) <[REDACTED] b6>; Freire, Maria C (NIH) <[REDACTED] b6>
Subject: ACTIV program to address SARS-CoV-2 variants

Hi Janet and Kevin,

See attached for the ACTIV proposal that captures all of the components for calendar year 2021. The budget request is (b) (5). I also attach a draft slide (still being reviewed, not for further distribution) that illustrates the relationship between the ACTIV program and the USG-only effort (now called SIG instead of SCIRAM). That reflects the discussions that have gone on for the last couple of days with Joe Menetski, Dan Jernigan, and John Mascola. Let me know what else I can do to help support this ACTIV proposal – I agree with you that this is of great urgency and needs to start right away.

Many thanks, Francis

From: Woodcock, Janet [REDACTED] b6
Sent: Thursday, January 14, 2021 4:57 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Bugin, Kevin (FDA/CDER) [REDACTED] b6
Subject: RE: variant effort

Good, I will need a \$\$ figure that rolls it all up ASAP if we are to get funding from us. jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, January 14, 2021 4:31 PM
To: Woodcock, Janet [REDACTED] b6
Subject: RE: variant effort

Hi Janet,

That's being actively worked on right now – SCIRAM can be the USG-only connection between agencies to be sure we are coordinating across HHS, and can deal with priority decisions where industry might have a conflict of interest. I'm expecting the merger that Joe Menetski (ACTIV) and Dan Jernigan (SCIRAM) are leading will produce a result in the next 18 hours.

Francis

From: Woodcock, Janet b [REDACTED]
Sent: Thursday, January 14, 2021 4:12 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: variant effort

How do we talk about the SCIRAM effort and its relationship to what you want to do with ACTIV? I think I can get some funding but will need to explain. jw

From: Eiss, Robert (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=707887EE7BA548E1A0AE55F683CE2017-EISSR]
Sent: 2/26/2021 7:05:19 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Hi Francis,

I reached out the the EU to invite a dialogue on the newly announced HERA Incubator and received the reply immediately below Irene Norstedt as you know is also the EU rep to HIROs

Recognizing demands on your schedule, is this a call that you and/or Carrie would want to have us arrange? Alternatively, I can reach out to Hugh Auchincloss and David Wholley

I can work with NIAID to assemble background and TPs

From: KAVANAGH Mary (EEAS-WASHINGTON) <[REDACTED]> b6
Sent: Friday, February 26, 2021 12:56 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Cc: Scharf, Sarah (NIH/FIC) [E] <[REDACTED]> b6 PEETERS Karin (EEAS-WASHINGTON) <[REDACTED]> b6
GARCIA-PASCUAL Julia (EEAS-WASHINGTON) <[REDACTED]> b6
Subject: RE: COVID-19 variants plan

Dear Robert,

Thanks again for your message and interest in the HERA initiative. It is in the very early stages of development right now. We would like to propose an informal bilateral discussion between Director Irene Norstedt (responsible for Health Research at the European Commission) and Dr Collins, where she could update on the status of HERA. She is also very interested to learn about the NIH relationship with BARDA and how it works.

It would also be the opportunity to discuss a couple of other very important areas:

- data sharing and the COVID-19 data platform
- the importance of cohorts and potential exchange of information.

Can you please let me know when such a call might be possible for Dr Collins?

Kind regards,

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, February 18, 2021 11:35 AM
To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

More complexity about Europe and GISAID.

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, February 18, 2021 9:35 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6

Cc: Freire, Maria (FNIH) [T] < [REDACTED] b6 > Menetski, Joseph (FNIH) [T] < [REDACTED] b6 >
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Dear Francis and David,

(b) (5)

Best,
Joe

From: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >
Sent: Thursday, February 18, 2021 7:55 AM
To: Wholley, David (FNIH) [T] < [REDACTED] b6 > Menetski, Joseph (FNIH) [T] < [REDACTED] b6 >
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

FYI, [REDACTED] (b) (5)

From: [REDACTED] b6 < [REDACTED] b6 >
Sent: Thursday, February 18, 2021 7:25 AM
To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >
Subject: Fwd: [EXTERNAL] COVID-19 : EU PPPs

Maybe we can interlink this w ACTIV seq

Sent from my iPhone

Begin forwarded message:

From: Prof Trevor M Jones CBE FMedSci < [REDACTED] b6 >
Date: February 18, 2021 at 07:17:17 EST
To: [REDACTED] b6 < [REDACTED] b6 > Andrew Plump < [REDACTED] b6 > [REDACTED] b6 < [REDACTED] b6 > paul stoffel < [REDACTED] b6 >
Cc: [REDACTED] b6 < [REDACTED] b6 > Geoff Frew < [REDACTED] b6 > Jill Payne < [REDACTED] b6 >
Subject: [EXTERNAL] COVID-19 : EU PPPs

For information.see below

Is any of this compatible with your Pandemic Preparedness initiative ?

If so can we establish an early dialogue with HERA

b6

.please note the final line re Vaccelerate

Trevor

On 17 February, the European Commission published a Communication titled '***HERA Incubator: Anticipating together the threat of COVID-19 variants***' which outlines the characteristics of a new bio-defence preparedness plan. The new programme has the objective of **preventing, mitigating and responding to the new COVID-19 variants also by boosting public-private-partnerships to revamp vaccine production**. The funding for this initiative would come from different resources: Horizon 2020, the new Horizon Europe, from the European Investment Bank through Horizon 2020's InnovFin Infectious Diseases Finance Facility (IDFF) and InvestEU. Please find the document attached and [at this link](#).

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The Communication outlines that genome sequencing needs to be enhanced and to achieve this objective, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization will play a vocal role to work towards **standardized genomic sequencing** across the EU and beyond.

In parallel with this Communication, a new EU-wide and EU-funded vaccine trial network called '***Vaccelerate***' is being launched in 16 EU Member States and five associated countries including Switzerland and Israel to exchange data and progressively include children and young adults as participants in clinical trials.

Prof Trevor M Jones CBE FMedSci

COLL0000012620

From: Eiss, Robert (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=707887EE7BA548E1A0AE55F683CE2017-EISSR]
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CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

I can go ahead and coordinate calendars. Will check with NIAID and assume the appropriate person is either Gray of Alan Embry, who leads the Respiratory Diseases Branch and has assumed Hilary Marston's COVID response responsibilities during her NSC detail

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Saturday, February 27, 2021 1:59 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6 Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Yes, I'd be willing to engage in a call. But I would want you, David W, and Joe M to join. And someone from NIAID – Hugh? Gray?

FC

From: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Sent: Friday, February 26, 2021 2:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

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Date: February 18, 2021 at 07:17:17 EST
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< b6 paul stoffel < b6
Cc: b6 b6 Geoff Frew < b6 Jill
Payne < b6
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Subject: Fwd: Pfizer ACTIV submission

Hope you will find this compelling
It's the first in class highly potent Sarcov2 protease inhibitors . We have human phase 1 data concluded .

Would be nice to see if we can work w NIH-ACTIV on this one

b6

Sent from my iPhone

Begin forwarded message:

From: b6 b6
Date: January 15, 2021 at 12:52:06 EST
To: "Adam, Stacey (FNIH) [T]" < b6
Cc: b6 b6 b6
b6 b6 b6
Subject: Pfizer ACTIV submission

Dear Stacey

I hope all is well. I'd like to give you the heads up that we are submitting PF-07304814, our IV protease inhibitor to the ACTIV portal today. We also have the IB that can be provided if required under the CDA that was signed this week.

Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best

b6

From: Woodcock, Janet [b6]
Sent: 2/26/2021 6:11:51 PM
To: Kessler, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5911e8dce1824359a3ad19b95ba2b632-David.Kessler]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfc346afd7671ee69f-Deydre.Teyh]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: FW: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment
Attachments: Draft BIRD Proceedings 25-02-2021 v 1.4.pdf

Another good reason to get ACTIV 6 up and running. Solid evidence still lacking. jw

From: Tess Lawrie <b6>
Sent: Friday, February 26, 2021 10:59 AM
To: Abernethy, Amy <b6> Anderson, Erika <b6> Yiannas, Frank
<b6> <b6> Tyler, James <b6> Tierney, Julia
<b6> Hinton, Denise <b6> Raza, Mark <b6>
Abdoo, Mark <b6> Araojo, Richard <b6> McMeekin, Judith
<b6> Rebello, Heidi <b6> Roth, Lauren
<b6> Tantillo, Andrew <b6> Vasisht, Kaveeta
<b6> Felberbaum, Michael <b6> Mair, Michael
<b6> Mettler, Erik <b6> Miller, Elizabeth
<b6> Rogers, Michael <b6> Cavazzoni, Patrizia
<b6> Marks, Peter <b6> Mayne, Susan
<b6> Pazdur, Richard <b6> <b6> Slikker,
William <b6> Solomon, Steven M <b6> <b6>
Stein, Peter <b6> Woodcock, Janet <Janet. b6> <b6>
Cc: claire Mock-Muñoz de Luna <b6> Ketan Gajjar <b6> Andy Bryant
<b6> Tony Tham <b6> Scott Mitchell <b6> Tina
Peers <b6>
Subject: [EXTERNAL] URGENT: The BIRD meeting proceedings and recommendation on covid-19 prevention and treatment

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Dr. Stein and FDA Colleagues,

We are writing to share with you the evidence to decision framework of the British Ivermectin Recommendation Development (BIRD) Meeting that was held on Saturday 20th February 2021 via Zoom from Bath, United Kingdom. The expert panel of health and allied professionals and other stakeholders included representatives from 16 countries, namely Argentina, Australia, Belgium, Botswana, Canada, France, Hungary, India, Ireland, Japan, Peru, Nigeria, South Africa, The Philippines, United States, United Kingdom. The ethos of the BIRD meeting was that of scientific rigour and transparency in the spirit of international collaboration towards a common goal – that of saving lives.

COLL0000012667

The recommendation was developed according *The WHO Handbook of Guideline Development (2014)*. BIRD panel conclusions are that ivermectin should be approved immediately for prevention and treatment of covid-19.

The BIRD recommendation on covid-19 prevention and treatment

The British Ivermectin Recommendation Development Panel recommends ivermectin for the prevention and treatment of covid-19 to reduce morbidity and mortality associated with covid-19 infection and to prevent covid-19 infection among those at higher risk.

The BIRD Steering Group has taken heed of the WHO statement on 'Developing global norms for sharing data and results during public health emergencies' that states that 'public disclosure of information of relevance to public health emergencies should not be delayed', and also notes the 'very great risks' that can occur from 'withholding data and results arising from analyses'. We are, therefore, sharing this evidence-to decision framework within just a few days of the BIRD meeting to avoid delay.

Further, due to the urgency related to the communication and dissemination of this recommendation that is aimed at saving thousands of lives daily, please forgive the limitations of the draft proceedings document attached. Information on the process and methods can be found among the annexes. An Executive Summary is being finalised and will be available on Monday.

We look forward to hearing from you soon and would be happy meet with you via teleconference if you think this will be helpful.

Please do not hesitate to contact us with any questions.

Kind regards,

Dr. Tess Lawrie, on behalf of the BIRD Steering Group and Recommendation Development Panel
Evidence-based Medicine Consultancy Ltd
e-bmc.co.uk

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 3/3/2021 2:54:23 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Re: Pfizer IV protease
Flag: Follow up

Yes – let's get the right people in the room and "make it happen".

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Date: Wednesday, March 3, 2021 at 9:51 AM
To: "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]> "Adam, Stacey (FNIH) [T]" <[REDACTED] b6 [REDACTED]> "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED] b6 [REDACTED]>
Subject: Pfizer IV protease

See response from Dolsten. Let's be creative here – can we do this?

FC

From: [REDACTED] b6 [REDACTED] <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, March 3, 2021 9:16 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: Re: [EXTERNAL] a few follow ups

Francis

We have completed SAD but have just a few patients w MAD due to enrollment is slow , however as it's IV- PK is predictable - it could likely start P2/3 ASAP and just have a 10-15 patient lead in phase w quick review followed by expansion - are you open to that, inwill check w our team and we may be able ready to go ASAP

We often do that in other areas

[REDACTED] b6 [REDACTED]

Sent from my iPhone

On Mar 3, 2021, at 09:11, Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] > wrote:

Hi [REDACTED] b6 [REDACTED]

I was just on a "war room" call with the ACTIV team and was confused with what I heard about the plans for the IV and oral protease. I was under the impression that the IV agent PF-07304814 would be ready to go almost immediately into ACTIV-3 – but the team seemed to indicate that the phase 1 trial wasn't completed yet. I was surprised, and thought there might have been confusion with the oral agent, which I know is doing through SAD and MAD right

now. Can you clarify? We are ready to put the IV agent into an arm of ACTIV-3 right away, and would love to get started with that.

Let me know, and thanks.

Francis

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 3/3/2021 2:59:53 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Pfizer IV protease

Thanks, Cliff,

I will add this to the agenda for our scheduled meeting with Pfizer on this Friday.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Lane, Cliff (NIH/NIAID) [E] <[b6]>
Sent: Wednesday, March 3, 2021 9:54 AM
To: Collins, Francis (NIH/OD) [E] <coll [b6]> Wholley, David (FNIH) [T] <[b6]> Adam, Stacey (FNIH) [T] <[b6]>
Subject: Re: Pfizer IV protease

Yes – let's get the right people in the room and "make it happen".

From: "Collins, Francis (NIH/OD) [E]" <[b6]>
Date: Wednesday, March 3, 2021 at 9:51 AM
To: "Wholley, David (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6], "Lane, Cliff (NIH/NIAID) [E]" <[b6]>
Subject: Pfizer IV protease

See response from Dolsten. Let's be creative here – can we do this?

FC

From: [b6] [b6]
Sent: Wednesday, March 3, 2021 9:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: [EXTERNAL] a few follow ups

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We often do that in other areas
b6

Sent from my iPhone

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Let me know, and thanks.

Francis

From: Bugin, Kevin [REDACTED]
Sent: 1/15/2021 9:57:13 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
Subject: RE: ACTIV program to address SARS-CoV-2 variants

Francis,

Who from NIH budget office could I work with to sort through all of this and how it would be provided? I'm starting to get question from HHS finance folks (good sign), but I'll need details on obligation dates, vehicles for transfers, contracts, etc. Can you connect me to a NIH budget guru to work with on this?

Kevin

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, January 14, 2021 11:25 PM
To: Woodcock, Janet <[REDACTED]>
Cc: Bugin, Kevin <[REDACTED]> Menetski, Joseph M (NIH) <[REDACTED]> Wholley, David N (NIH) <[REDACTED]> Freire, Maria C (NIH) <[REDACTED]>
Subject: ACTIV program to address SARS-CoV-2 variants

Hi Janet and Kevin,

See attached for the ACTIV proposal that captures all of the components for calendar year 2021. The budget request is \$19.375M. I also attach a draft slide (still being reviewed, not for further distribution) that illustrates the relationship between the ACTIV program and the USG-only effort (now called SIG instead of SCIRAM). That reflects the discussions that have gone on for the last couple of days with Joe Menetski, Dan Jernigan, and John Mascola. Let me know what else I can do to help support this ACTIV proposal – I agree with you that this is of great urgency and needs to start right away.

Many thanks, Francis

From: Woodcock, Janet [REDACTED]
Sent: Thursday, January 14, 2021 4:57 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED]
Cc: Bugin, Kevin (FDA/CDER) [REDACTED]
Subject: RE: variant effort

Good, I will need a \$\$ figure that rolls it all up ASAP if we are to get funding from us. jw

From: Collins, Francis (NIH/OD) [E] [REDACTED]
Sent: Thursday, January 14, 2021 4:31 PM
To: Woodcock, Janet [REDACTED]
Subject: RE: variant effort

Hi Janet,

That's being actively worked on right now – SCIRAM can be the USG-only connection between agencies to be sure we are coordinating across HHS, and can deal with priority decisions where industry might have a conflict

COLL0000012726

of interest. I'm expecting the merger that Joe Menetski (ACTIV) and Dan Jernigan (SCIRAM) are leading will produce a result in the next 18 hours.

Francis

From: Woodcock, Janet <[REDACTED]> b6

Sent: Thursday, January 14, 2021 4:12 PM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6

Subject: variant effort

How do we talk about the SCIRAM effort and its relationship to what you want to do with ACTIV? I think I can get some funding but will need to explain. jw

From: Wood, Gretchen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=549F390B39D044A8B5D1E0E1A8F76C1F-WOODGS]
Sent: 3/5/2021 3:28:21 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs
Flag: Follow up

Good morning, Francis,

Please see note below from Rob about this call. Okay to schedule for the March 17th time slot with just you and Dr. Norstedt?

Thank you,

Gretchen

From: Robert Eiss <[REDACTED] b6>
Date: Friday, March 5, 2021 at 9:43 AM
To: Gretchen Wood <[REDACTED] b6>
Subject: Re: [EXTERNAL] COVID-19 : EU PPPs

Hi Gretchen,

Dr. Norstedt has asked if the 17th might be confirmed

However, she has requested this be a one-on-one call. Since this likely is not Dr Collins' preference, should we reconfirm with him?

Perhaps he could agree to a brief call with an expectation that Fogarty would then arrange a follow-up between her team and NIAID and FNIH key colleagues

(Nothing is ever straightforward with the EC)

Sent from my iPhone

On Mar 1, 2021, at 4:30 PM, Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6> wrote:

Hi Rob,

Please offer the following:

March 12	9:00 AM-9:30 AM ET/3:00 PM-3:30 PM CET
March 15	10:30 AM-11:00 AM ET/4:30 PM-5:00 PM CET
March 17	10:00 AM-10:30 AM ET/4:00 PM-4:30 PM CET

Thank you,

Gretchen

COLL0000012770

From: Robert Eiss <[REDACTED] b6>
Date: Monday, March 1, 2021 at 11:50 AM
To: Gretchen Wood <[REDACTED] b6>
Subject: Re: [EXTERNAL] COVID-19 : EU PPPs

Hi Gretchen,

No time sensitivity with this. Many thanks

Sent from my iPhone

On Mar 1, 2021, at 11:49 AM, Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6> wrote:

Good morning, Rob,

Sure, happy to look for times. Is there a time sensitivity to this or can it be later this week or next week?

Thank you,

Gretchen

From: Robert Eiss <[REDACTED] b6>
Date: Monday, March 1, 2021 at 10:12 AM
To: Gretchen Wood <[REDACTED] b6>
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

Hi Gretchen,

See below. At your convenience are you able to propose a couple dates and times for a 30 minute meeting with Irene Norstedt of the European Commission in Brussels?

Thanks

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Saturday, February 27, 2021 1:59 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED] b6> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Yes, I'd be willing to engage in a call. But I would want you, David W, and Joe M to join. And someone from NIAID – Hugh? Gray?

FC

From: Eiss, Robert (NIH/FIC) [E] <[REDACTED] b6>
Sent: Friday, February 26, 2021 2:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Hi Francis,

I reached out the the EU to invite a dialogue on the newly announced HERA Incubator and received the reply immediately below Irene Norstedt as you know is also the EU rep to HIROs

Recognizing demands on your schedule, is this a call that you and/or Carrie would want to have us arrange? Alternatively, I can reach out to Hugh Auchincloss and David Wholley

I can work with NIAID to assemble background and TPs

From: KAVANAGH Mary (EEAS-WASHINGTON) <[REDACTED]> b6
Sent: Friday, February 26, 2021 12:56 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Cc: Scharf, Sarah (NIH/FIC) [E] <[REDACTED]> b6; PEETERS Karin (EEAS-WASHINGTON) <[REDACTED]> b6 GARCIA-PASCUAL Julia (EEAS-WASHINGTON) <[REDACTED]> b6
Subject: RE: COVID-19 variants plan

Dear Robert,

Thanks again for your message and interest in the HERA initiative. It is in the very early stages of development right now. We would like to propose an informal bilateral discussion between Director Irene Norstedt (responsible for Health Research at the European Commission) and Dr Collins, where she could update on the status of HERA. She is also very interested to learn about the NIH relationship with BARDA and how it works.

It would also be the opportunity to discuss a couple of other very important areas:

- data sharing and the COVID-19 data platform
- the importance of cohorts and potential exchange of information.

Can you please let me know when such a call might be possible for Dr Collins?

Kind regards,

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, February 18, 2021 11:35 AM
To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6 Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

More complexity about Europe and GISAID.

From: Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, February 18, 2021 9:35 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Freire, Maria (FNIH) [T] <[REDACTED]> b6 Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Dear Francis and David,

I think we do need to link with the EU, but the issues that need to be addressed are the same (rapid sharing of samples and public release of sequence info).

This proposal appears to be a tight collaboration with WHO and WHO runs GISAID, so if they enforce that database as the only approach, it ties NIH hands in the initial analysis. Reading the link to the full document, this appears to be the case, which is really exclusionary to NCBI researchers.

Perhaps we can suggest that the US be considered a Member state in this initiative, so that it has the same rights as the others? I think this is a policy and State Department issue that needs to be addressed at the highest levels.

Other than the first item, the other work packages described below are really part of the preparedness proposal we generated a few weeks ago. They are not really about surveillance or variant verification. Having said that, it would be helpful to connect on those too, but probably not a TRACE connection.

Best,
Joe

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Thursday, February 18, 2021 7:55 AM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]> Menetski, Joseph (FNIH) [T]
<[REDACTED] b6 [REDACTED]>
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

FYI, what do you think about a linkage with Europe?

From: [REDACTED] b6 [REDACTED] b6 [REDACTED]
Sent: Thursday, February 18, 2021 7:25 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: Fwd: [EXTERNAL] COVID-19 : EU PPPs

Maybe we can interlink this w ACTIV seq

Sent from my iPhone

Begin forwarded message:

From: Prof Trevor M Jones CBE FMedSci
<[REDACTED] b6 [REDACTED]>
Date: February 18, 2021 at 07:17:17 EST
To: [REDACTED] b6 [REDACTED] Andrew Plump
[REDACTED] b6 [REDACTED] b6 [REDACTED]
<[REDACTED] b6 [REDACTED]> paul stoffel [REDACTED] b6 [REDACTED]
Cc: [REDACTED] b6 [REDACTED] b6 [REDACTED] Geoff Frew
<[REDACTED] b6 [REDACTED]> Jill Payne
<[REDACTED] b6 [REDACTED]>
Subject: [EXTERNAL] COVID-19 : EU PPPs

For information.see below

Is any of this compatible with your Pandemic Preparedness initiative ?

If so can we establish an early dialogue with HERA

b6 ..please note the final line re Vaccellarate

Trevor

On 17 February, the European Commission published a Communication titled '***HERA Incubator: Anticipating together the threat of COVID-19 variants***' which outlines the characteristics of a **new bio-defence preparedness plan**. The new programme has the objective of **preventing, mitigating and responding to the new COVID-19 variants also by boosting public-private-partnerships to revamp vaccine production**. The funding for this initiative would come from different resources: Horizon 2020, the new Horizon Europe, from the European Investment Bank through Horizon 2020's InnovFin Infectious Diseases Finance Facility (IDFF) and InvestEU. Please find the document attached and [at this link](#).

The programme will serve as the vanguard for the upcoming European Health Emergency Preparedness and Response Authority (HERA), and it is considered as a step further to ensure that action is taken with immediate effect on different fronts:

- Rapid detection of variants;
- Swift adaptation of vaccines;
- Setting up a European Clinical Trials Network;
- Fast-tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures; and
- Enable upscaling of production of existing, adapted or novel COVID-19 vaccines.

The Communication outlines that genome sequencing needs to be enhanced and to achieve this objective, the European Centre for

Disease Prevention and Control (ECDC) and the World Health Organization will play a vocal role to work towards **standardized genomic sequencing** across the EU and beyond.

In parallel with this Communication, a new EU-wide and EU-funded vaccine trial network called 'Vaccelerate' is being launched in 16 EU Member States and five associated countries including Switzerland and Israel to exchange data and progressively include children and young adults as participants in clinical trials.

Prof Trevor M Jones CBE FMedSci

From: Eiss, Robert (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=707887EE7BA548E1A0AE55F683CE2017-EISSR]
Sent: 3/5/2021 3:39:00 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: [EXTERNAL] COVID-19 : EU PPPs

Flag: Follow up

Hi Francis

I'll explore further, to confirm if I can join to support follow up

Sent from my iPhone

On Mar 5, 2021, at 10:30 AM, Collins, Francis (NIH/OD) [E] <[REDACTED]> wrote:

OK, though I don't understand why I couldn't have Rob join with me.

FC

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED]>
Sent: Friday, March 5, 2021 10:28 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

Good morning, Francis,

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Thank you,

Gretchen

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Subject: Re: [EXTERNAL] COVID-19 : EU PPPs

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COLL0000012771

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Gretchen

From: Robert Eiss <[REDACTED]>
Date: Monday, March 1, 2021 at 11:50 AM
To: Gretchen Wood <[REDACTED]>
Subject: Re: [EXTERNAL] COVID-19 : EU PPPs

Hi Gretchen,

No time sensitivity with this. Many thanks

Sent from my iPhone

On Mar 1, 2021, at 11:49 AM, Wood, Gretchen (NIH/OD) [E] <[REDACTED]> wrote:

Good morning, Rob,

Sure, happy to look for times. Is there a time sensitivity to this or can it be later this week or next week?

Thank you,

Gretchen

From: Robert Eiss <[REDACTED]>
Date: Monday, March 1, 2021 at 10:12 AM
To: Gretchen Wood <[REDACTED]>
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

Hi Gretchen,

See below. At your convenience are you able to propose a couple dates and times for a 30 minute meeting with Irene Norstedt of the European Commission in Brussels?

Thanks

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Saturday, February 27, 2021 1:59 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Yes, I'd be willing to engage in a call. But I would want you, David W, and Joe M to join. And someone from NIAID – Hugh? Gray?

FC

From: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Sent: Friday, February 26, 2021 2:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6; Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Hi Francis,

I reached out the the EU to invite a dialogue on the newly announced HERA Incubator and received the reply immediately below Irene Norstedt as you know is also the EU rep to HIROs

Recognizing demands on your schedule, is this a call that you and/or Carrie would want to have us arrange? Alternatively, I can reach out to Hugh Auchincloss and David Wholley

I can work with NIAID to assemble background and TPs

From: KAVANAGH Mary (EEAS-WASHINGTON) <[REDACTED]> b6
Sent: Friday, February 26, 2021 12:56 PM
To: Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6
Cc: Scharf, Sarah (NIH/FIC) [E] <[REDACTED]> b6; PEETERS Karin (EEAS-WASHINGTON) <[REDACTED]> b6; GARCIA-PASCUAL Julia (EEAS-WASHINGTON) <[REDACTED]> b6
Subject: RE: COVID-19 variants plan

Dear Robert,
Thanks again for your message and interest in the HERA initiative. It is in the very early stages of development right now. We would like to propose an informal bilateral discussion between Director Irene Norstedt (responsible for Health Research at the European Commission) and Dr Collins, where she could update on the status of HERA. She is also very interested to learn about the NIH relationship with BARDA and how it works.

It would also be the opportunity to discuss a couple of other very important areas:

- data sharing and the COVID-19 data platform
- the importance of cohorts and potential exchange of information.

Can you please let me know when such a call might be possible for Dr Collins?

Kind regards,

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Sent: Thursday, February 18, 2021 11:35 AM
To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6 > Eiss, Robert (NIH/FIC) [E] <[REDACTED] b6 >
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

More complexity about Europe and GISAID.

From: Menetski, Joseph (FNIH) [T] <[REDACTED] b6 >
Sent: Thursday, February 18, 2021 9:35 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 > Wholley, David (FNIH) [T] <[REDACTED] b6 >
Cc: Freire, Maria (FNIH) [T] <[REDACTED] b6 > Menetski, Joseph (FNIH) [T] <[REDACTED] b6 >
Subject: RE: [EXTERNAL] COVID-19 : EU PPPs

Dear Francis and David,

(b) (5)



Best,
Joe

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, February 18, 2021 7:55 AM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Menetski, Joseph (FNIH) [T] <[REDACTED]> b6
Subject: FW: [EXTERNAL] COVID-19 : EU PPPs

FYI, [REDACTED] (b) (5)

From: [REDACTED] b6 [REDACTED] b6
Sent: Thursday, February 18, 2021 7:25 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: Fwd: [EXTERNAL] COVID-19 : EU PPPs

Maybe we can interlink this w ACTIV seq

Sent from my iPhone

Begin forwarded message:

From: Prof Trevor M Jones CBE FMedSci
[REDACTED] b6 >
Date: February 18, 2021 at 07:17:17 EST
To: [REDACTED] b6 Andrew Plump
<[REDACTED] b6 [REDACTED] b6
<[REDACTED] b6 paul stoffel
<[REDACTED] b6
Cc: [REDACTED] b6 [REDACTED] b6
Geoff Frew <[REDACTED] b6 [REDACTED] Jill Payne
[REDACTED] b6
Subject: [EXTERNAL] COVID-19 : EU PPPs

For information.see below

Is any of this compatible with your Pandemic Preparedness initiative ?

If so can we establish an early dialogue with HERA

[REDACTED] b6 ..please note the final line re Vaccellarate

Trevor

On 17 February, the European Commission published a Communication titled '***HERA Incubator: Anticipating together the threat of COVID-19 variants***' which outlines the characteristics of a **new bio-defence preparedness plan**. The new programme has the objective of **preventing, mitigating and responding to the new COVID-19 variants also by boosting public-private-partnerships to revamp vaccine production**. The funding for this initiative would come from different resources: Horizon 2020, the new Horizon Europe, from the European Investment Bank through Horizon 2020's InnovFin Infectious Diseases Finance Facility (IDFF) and InvestEU. Please find the document attached and [at this link](#). The programme will serve as the vanguard for the upcoming European Health Emergency Preparedness and Response Authority (HERA), and it is considered as a step further to ensure that action is taken with immediate effect on different fronts:

- Rapid detection of variants;
- Swift adaptation of vaccines;
- Setting up a European Clinical Trials Network;
- Fast-tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures; and
- Enable upscaling of production of existing, adapted or novel COVID-19 vaccines.

The Communication outlines that genome sequencing needs to be enhanced and to achieve this objective, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization will play a vocal role to work towards **standardized genomic sequencing** across the EU and beyond.

In parallel with this Communication, a new EU-wide and EU-funded vaccine trial network called '*Vaccelerate*' is being launched in 16 EU Member States and five associated countries including Switzerland and Israel to exchange data and progressively include children and young adults as participants in clinical trials.

From: b6 b6
Sent: 1/16/2021 3:34:42 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission
Flag: Follow up

Hi
Yes , we have acceptable phase 1 safety and tolerability profile for the IV. It's also additive to Remdesivir

We will submit a data package to ACTIV

You are a mind reader , we have an oral SARSCov2 protease inhibitor drug with great preclinical profile that's starting phase 1 soon . The profile suggests it's equally active against all known new mutants . We can potentially bring that also for an NIH-ACTIV phase 2 partnership soon . As it's a pan Corona virus profile , it provides also great pandemic preparedness . May fit very well w the acceleration of vaccines and therapeutics for covid19 in 2021
Happy to discuss
b6

Sent from my iPhone

On Jan 16, 2021, at 09:44, Collins, Francis (NIH/OD) [E] < b6 > wrote:

Hey b6

This sounds really interesting! I assume Phase 1 data looks good for any safety signal. Is the preclinical data available somewhere? I'd bet you are also working on an oral or SQ alternative?

Best, Francis

From: b6 b6
Sent: Friday, January 15, 2021 1:10 PM
To: Collins, Francis (NIH/OD) [E] < b6 >
Subject: Fwd: Pfizer ACTIV submission

Hope you will find this compelling
It's the first in class highly potent Sarcov2 protease inhibitors . We have human phase 1 data concluded .

Would be nice to see if we can work w NIH-ACTIV on this one

b6

Sent from my iPhone

Begin forwarded message:

From: [REDACTED] b6 [REDACTED] b6
Date: January 15, 2021 at 12:52:06 EST
To: "Adam, Stacey (FNIH) [T]" [REDACTED] b6
Cc: [REDACTED] b6, [REDACTED] b6
[REDACTED] b6 [REDACTED] b6 [REDACTED] b6
Subject: Pfizer ACTIV submission

Dear Stacey

I hope all is well. I'd like to give you the heads up that we are submitting PF-07304814, our IV protease inhibitor to the ACTIV portal today. We also have the IB that can be provided if required under the CDA that was signed this week.

Scott White is the clinical lead for this program and will be the submitter. We are hopeful that there will be an interest to collaborate on this first in class treatment option for COVID-19. Please let us know if you have any questions.

All the best

[REDACTED] b6

From: b6 b6
Sent: 1/16/2021 4:44:16 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] RE: Pfizer ACTIV submission
Flag: Follow up

Francis

One thing that came to my mind , do you regard ACTIV as the main potential way to collaborate between NIH-Pfizer on the IV and oral SARSCov2 protease inhibitor (PI) drugs that will be going into phase two studies now (iv) or soon (oral)?

Do you foresee any alternative potential structure government - company that would be more of a closer bilateral collaboration, similarly as you did w MODERNA in the vaccine? I assume the new administrator may also use BARDA like pathways

Just thought it would be good to consider which alternative may be best suited given the dire pandemic and this is the first PI.

What's your thoughts ?

b6

Sent from my iPhone

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Sent from my iPhone

COLL0000012825

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From: b6 " b6
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Cc: b6 b6 , b6
b6 b6 " b6
Subject: Pfizer ACTIV submission

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All the best

b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/15/2021 8:36:36 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Chen, Helen [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]
Subject: RE: [EXTERNAL] concern about progress with IV anti-protease

Thanks, Francis! We'll pass this on selectively to those with a need to know on the ACTIV-3 team and expect some more promising perspective from the Pfizer team on Friday.

From: Collins, Francis (NIH/OD) [E] < b6 >
Sent: Monday, March 15, 2021 4:12 PM
To: Wholley, David (FNIH) [T] < b6 > Freire, Maria (FNIH) [T] < b6 > Tabak, Lawrence (NIH/OD) [E] < b6 > Lane, Cliff (NIH/NIAID) [E] < b6 > Anderson, James (NIH/OD) [E] < b6 > Rutter, Joni (NIH/NCATS) [E] < b6 > Patterson, Amy (NIH/NHLBI) [E] < b6 > Parker, Ashley (NIH/OD) [E] < b6 >
Subject: FW: [EXTERNAL] concern about progress with IV anti-protease

Quite a different story from Dolsten....

From: b6 < b6 >
Sent: Monday, March 15, 2021 3:46 PM
To: Collins, Francis (NIH/OD) [E] b6
Subject: Re: [EXTERNAL] concern about progress with IV anti-protease

Francis

Getting feedback , -

1 I think we will have next week cleared P2/3 oral low dose . One can consider start P2/3 w low dose (it's 3-4x EC90) and possibly add soon a higher dose

2 IV this week clearing low dose w relevant exposure . We could consider start ACTIV w that dose while we clear a second higher dose to be added

Will confirm details on material available but think all will be fine

Sent from my iPhone

On Mar 15, 2021, at 11:08, Collins, Francis (NIH/OD) [E] b6 > wrote:

Hi b6

I heard some news this morning in the ACTIV War Room that progress in getting the Pfizer IV anti-protease into ACTIV-3 is going more slowly than expected. Apparently there is difficulty getting the last few volunteers for phase 1? Can we help with that? I also heard there might be supply issues, and that might mean delaying South African sites until July?

What can we do to accelerate this?

Best, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/16/2021 12:37:18 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: progress with IV anti-protease drug (PI)

Working on the answers. Thanks

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, March 15, 2021 9:04 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Freire, Maria (FNIH) [T] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Anderson, James (NIH/OD) [E] <[REDACTED]> b6 Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> b6 Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: progress with IV anti-protease drug (PI)

Hi David,

See Dolsten response below. Need advice about response.

Tx, FC

From: [REDACTED] b6 [REDACTED] b6
Sent: Monday, March 15, 2021 8:09 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: progress with IV anti-protease drug (PI)

Hi Francis

I am following up w some response to your email:

1 IV PI drug ACTIV-3 P2/3 pot start mid April

COLL0000012936

We are currently looking at moving the ACTIV-3 IV protease inhibitor drug (PI) start from mid June to mid-late April for low dose arm ; with the high dose mid May. Would that work for you ?

2 Oral drug pot early May ACTIV P2/3 start

For the Oral program we are carrying the mid May start: the team are actively working on pulling that in to early May. We are relatively optimistic that we can accomplish this .

The following is the list of action items that it would be useful for the NIH to help us with:

- Expedite FDA review for cohort 1 (less than 5 days, being sent on the 5th April)
- Need clarity on ex US sites for ACTIV-3 and the timing to bring them on board for our CMC planning
- Work with the three ACTIV-3/Pfizer shared sites to allow investigators into the 1001 study (high dose MAD) to faster allow selection of high dose into P2/3 study
- Accept current 12-month shelf life as per Pfizer SOP
- Start ACTIV-2 discussions regarding oral PI with Pfizer so we can initiate labelling discussions

Pls advise how we keep the momentum and any follow up that you suggest

Best
b6 and Pfizer team

Sent from my iPhone

On Mar 15, 2021, at 15:46, b6 b6 wrote:

Francis

Getting feedback , -

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What can we do to accelerate this?

Best, Francis

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Sent: 3/16/2021 8:40:46 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: progress with IV anti-protease drug (PI)

Hi Francis:

(b) (4)
(b) (4)

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(b) (4)

-
-
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(b) (4)

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Sent: 3/17/2021 8:27:18 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Hi Francis:

(b) (5)

(b) (5); the next meeting with them, as I mentioned on this morning's war room, will be Friday morning at 10 AM.

David

From: Collins, Francis (NIH/OD) [E] <(b) (5)>
Sent: Tuesday, March 16, 2021 9:36 PM
To: Wholley, David (FNIH) [T] <(b) (5)> Freire, Maria (FNIH) [T] <(b) (5)> Tabak, Lawrence (NIH/OD) [E] <(b) (5)> Lane, Cliff (NIH/NIAID) [E] <(b) (5)> Anderson, James (NIH/OD) [E] <(b) (5)> Rutter, Joni (NIH/NCATS) [E] <(b) (5)> Patterson, Amy (NIH/NHLBI) [E] <(b) (5)> Parker, Ashley (NIH/OD) [E] <(b) (5)>
Subject: FW: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

From: (b) (5)
Sent: Tuesday, March 16, 2021 9:05 PM
To: Collins, Francis (NIH/OD) [E] <(b) (5)>
Subject: Re: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Francis

Many thanks for helpful answers
I will follow up on your requests
Look forward to work closely together on this
(b) (5)

COLL0000012970

Sent from my iPhone

On Mar 16, 2021, at 21:02, Collins, Francis (NIH/OD) [E] [REDACTED] wrote:

Hi [REDACTED]

Thanks so much for your prompt response. I've done some checking with our ACTIV teams, and my responses to your observations and questions are in italics below.

Best, Francis

From: [REDACTED] b6 [REDACTED]
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[REDACTED] (b) (4)

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- [REDACTED]
- [REDACTED]

(b) (4)

-
-

Pls advise how we keep the momentum and any follow up that you suggest

(b) (4)

Best

b6 and Pfizer team

Sent from my iPhone

On Mar 15, 2021, at 15:46, b6 b6 wrote:

Francis

Getting feedback , -

1 I think we will have next week cleared P2/3 oral low dose . One can consider start P2/3 w low dose (it's 3-4x EC90) and possibly add soon a higher dose

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Sent from my iPhone

On Mar 15, 2021, at 11:08, Collins, Francis (NIH/OD) [E]

< b6 wrote:

Hi b6

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What can we do to accelerate this?

Best, Francis

COLL0000012970

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/17/2021 10:30:15 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)
Flag: Follow up

I'd assume so. How about if I ask Kevin Bugin whom he's talked with about this—if anyone.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, March 17, 2021 6:12 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

(b) (5)

FC

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Sent: Wednesday, March 17, 2021 4:27 PM
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Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Hi Francis:

(b) (5)

[REDACTED] (b) (5) ; the next meeting with them, as I mentioned on this morning's war room, will be Friday morning at 10 AM.

David

COLL0000012984

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, March 16, 2021 9:36 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Anderson, James (NIH/OD) [E] <[REDACTED]> b6 Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> b6 Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

From: [REDACTED] b6 [REDACTED] b6
Sent: Tuesday, March 16, 2021 9:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: Re: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Francis

Many thanks for helpful answers
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Look forward to work closely together on this
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Sent from my iPhone

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Hi [REDACTED] b6
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From: [REDACTED] b6 [REDACTED] b6
Sent: Monday, March 15, 2021 8:09 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: progress with IV anti-protease drug (PI)

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Sent: 3/17/2021 10:44:28 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Sent the note already. Also asked if there is a dollar amount yet...

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, March 17, 2021 6:41 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Yes please

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, March 17, 2021 6:30 PM
To: Collins, Francis (NIH/OD) [E] <coll[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

I'd assume so. How about if I ask Kevin Bugin whom he's talked with about this—if anyone.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
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To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

It would be truly unfortunate if the oral anti-protease was slowed down. To whom does this funding request go at this point? Kessler?

FC

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Wednesday, March 17, 2021 4:27 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6

Maria (FNIH) [T] < [REDACTED] b6

Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Hi Francis:

(b) (5)

[REDACTED] (b) (5) ; the next meeting with them, as I mentioned on this morning's war room, will be Friday morning at 10 AM.

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Subject: FW: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

From: [REDACTED] b6 [REDACTED] b6

Sent: Tuesday, March 16, 2021 9:05 PM

To: Collins, Francis (NIH/OD) [E] < [REDACTED] b6

Subject: Re: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

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I will follow up on your requests

Look forward to work closely together on this

[REDACTED] b6

Sent from my iPhone

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Best, Francis

COLL0000012985

From: b6
Sent: Monday, March 15, 2021 8:09 PM
To: Collins, Francis (NIH/OD) [E] <b6>
Subject: progress with IV anti-protease drug (PI)

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b6 and Pfizer team

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Sent: 3/17/2021 10:46:40 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: Confidential to the two of you. Re: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

Francis/Larry – I am just sending this to the two of you. It might be a bit sensitive.

You are likely aware there is a fairly substantial initiative for anti-viral therapy being discussed for which funds appear to be available and for which Carl Dieffenbach (Director, Division of AIDS [DAIDS], NIAID), working with John Martin (formerly of Gilead), has the lead. I have a degree of awareness but little in the way of detail.

As we transition from non-stop emergency response to a bit more of a “return to normal” response it might make sense to see whether or not an additional arm for ACTIV-2 (sponsored by DAIDS) would be something that might be funded via that initiative.

As an additional thought – it would seem that an oral protease inhibitor could potentially be an arm in ACTIV-6.

Cliff

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> b6
Date: Wednesday, March 17, 2021 at 6:12 PM
To: "Wholley, David (FNIH) [T]" <[REDACTED]> b6
Cc: "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> b6 Lawrence Tabak <[REDACTED]> b6 "Freire, Maria (FNIH) [T]" <[REDACTED]> b6
Subject: RE: [EXTERNAL] FW: progress with IV anti-protease drug (PI)

(b) (5)

FC

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Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
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COLL0000012986

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Sent: 3/17/2021 11:58:39 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
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Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor
Flag: Follow up

OK, (b) (5)

From: Bugin, Kevin < b6 >
Sent: Wednesday, March 17, 2021 7:25 PM
To: Wholley, David (FNIH) [T] < b6 >
Cc: Kim, Peter (NIH/NIAID) [E] < b6 > Lane, Cliff (NIH/NIAID) [E] < b6 > Johnson, Martin S. (NIH/NIAID) [E] < b6 >
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi David,

Looping in Martin Johnson.

So, my understanding is that (b) (5)

I guess two points for Dr. Collins:

(1) (b) (5)

(2)

Hope this is helpful!

Kevin

From: Wholley, David (FNIH) [T] b6 >
Sent: Wednesday, March 17, 2021 6:43 PM
To: Bugin, Kevin b6 >
Cc: Kim, Peter S (NIH) b6 >; Lane, Henry C (NIH) b6
Subject: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin—

Francis has agreed to help push this as a priority. He's asked who you've spoken with so far about this and who actually ultimately approves it (he's guessing David Kessler but wanted to make sure). Also, Peter, is there any kind of estimate of what NIAID would need to do this? Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6 | fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 3/18/2021 12:08:08 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Subject: Re: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

I let Neil know that he should schedule the briefings as soon as the Operation Team is ready for them. I assume they are referring to the memos that needed to be redone after the transition and the newest one for ACTIV 6.
Larry

From: "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Date: Wednesday, March 17, 2021 at 7:58 PM
To: Francis Collins <[REDACTED] b6 [REDACTED]> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Cc: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>, "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED] b6 [REDACTED]>, "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> "Kim, Peter (NIH/NIAID) [E]" <[REDACTED] b6 [REDACTED]>
Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

OK, [REDACTED] (b) (5) [REDACTED]
[REDACTED] (b) (5) [REDACTED]

From: Bugin, Kevin <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, March 17, 2021 7:25 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Cc: Kim, Peter (NIH/NIAID) [E] <[REDACTED] b6 [REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 [REDACTED]> Johnson, Martin S. (NIH/NIAID) [E] <[REDACTED] b6 [REDACTED]>
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi David,

Looping in Martin Johnson.

So, my understanding is that [REDACTED] (b) (5) [REDACTED]
[REDACTED] (b) (5) [REDACTED]

I guess two points for Dr. Collins:

(1)

(b) (5)

(2)

Hope this is helpful!

Kevin

From: Wholley, David (FNIH) [T] b6 >

Sent: Wednesday, March 17, 2021 6:43 PM

To: Bugin, Kevin b6

Cc: Kim, Peter S (NIH) b6 Lane, Henry C (NIH) b6

Subject: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin—

Francis has agreed to help push this as a priority. He's asked who you've spoken with so far about this and who actually ultimately approves it (he's guessing David Kessler but wanted to make sure). Also, Peter, is there any kind of estimate of what NIAID would need to do this? Thanks, David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

b6 | fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852



COLL0000012994

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 3/18/2021 12:16:27 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Ok – (b) (5)

From: Francis Collins < (b) (5) >
Date: Wednesday, March 17, 2021 at 8:13 PM
To: "Tabak, Lawrence (NIH/OD) [E]" < (b) (5) >
Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

This is what Cliff was referring to – (b) (5) (b) (5)

From: Wholley, David (FNIH) [T] < (b) (5) >
Sent: Wednesday, March 17, 2021 7:59 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) > Tabak, Lawrence (NIH/OD) [E] < (b) (5) >
Cc: Freire, Maria (FNIH) [T] < (b) (5) > Lane, Cliff (NIH/NIAID) [E] < (b) (5) > Parker, Ashley (NIH/OD) [E] < (b) (5) > Kim, Peter (NIH/NIAID) [E] < (b) (5) >
Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

OK, (b) (5)

From: Bugin, Kevin (b) (5)
Sent: Wednesday, March 17, 2021 7:25 PM
To: Wholley, David (FNIH) [T] (b) (5) >
Cc: Kim, Peter (NIH/NIAID) [E] (b) (5) ; Lane, Cliff (NIH/NIAID) [E] (b) (5) >; Johnson, Martin S. (NIH/NIAID) [E] (b) (5) >
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi David,

Looping in Martin Johnson.

So, my understanding is that (b) (5)

I guess two points for Dr. Collins:

COLL0000012995

(1)

(b) (5)

(2)

Hope this is helpful!

Kevin

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, March 17, 2021 6:43 PM
To: Bugin, Kevin <b6>
Cc: Kim, Peter S (NIH) <b6>; Lane, Henry C (NIH) b6 >
Subject: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

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Hi Kevin—

Francis has agreed to help push this as a priority. He's asked who you've spoken with so far about this and who actually ultimately approves it (he's guessing David Kessler but wanted to make sure). Also, Peter, is there any kind of estimate of what NIAID would need to do this? Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6 | fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



COLL0000012995

From: Koroshetz, Walter (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E8338DD7CDCD432E986961F1548C5EC6-KOROSHETZW]
Sent: 3/18/2021 8:15:28 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Message
Attachments: vaccination in long haulers.pdf

Small numbers but a paper in bioarchive suggesting a beneficial effect of vaccination on PASC symptoms. Need to know more.

Tony- any chance the virus is hiding out somewhere, and the vaccine response targets it?

walter

From: Collins, Francis (NIH/OD) [E] <[REDACTED]>
Sent: Thursday, March 18, 2021 4:11 PM
To: Gibbons, Gary (NIH/NHLBI) [E] <[REDACTED]> Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]>
Koroshetz, Walter (NIH/NINDS) [E] <[REDACTED]> Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]>
Cc: Wholley, David (FNIH) [T] <[REDACTED]>
Subject: RE: Message

Hi Gary,

I agree the last couple of ACTIV Leadership Meetings have been very significant, and this conversation about PASC – albeit brief – is good example. Your list is good. One other item to add – there are now anecdotal reports of individuals suffering from PASC months after natural infection with COVID-19, who say they had a dramatic recovery after vaccination. Probably that's not going to be a widespread phenomenon, but it should certainly be tracked.

Yes, a brief executive summary of PASC for ACTIV would be useful. I'm looping in David Wholley.

Francis

From: Gibbons, Gary (NIH/NHLBI) [E] <[REDACTED]>
Sent: Thursday, March 18, 2021 2:17 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]>;
Koroshetz, Walter (NIH/NINDS) [E] <[REDACTED]> >; Fauci, Anthony (NIH/NIAID) [E] <[REDACTED]>
Subject: RE: Message

Hi Francis,

Thanks for sharing this ACTIV meeting follow-up query.

COLL0000013026

The team will need to give this further brainstorming/dialogue; but in short, I suspect we can all agree that b6 basic premise/hypothesis is quite plausible and worthy of testing.

A few quick, first-pass considerations come to mind:

- What is the clinical spectrum and natural history of SARS-CoV2 **RE-infection** in patients with PASC compared to non-PASC/COVID-positive comparator controls in the NIH SARS-CoV2 Recovery Meta-Cohort?
- How can we best leverage the well phenotyped participants in the SARS-CoV2 Recovery Meta-Cohort to better understand the clinical/sub-clinical consequences of *re-infection* by original or new variants?

>>[I think the PASC platform being constructed could be well poised to address this question].

- Are there differences in the incidence/prevalence of PASC in the pre-vaccine phase of the pandemic vs the 'post-vaccine' phase of the pandemic?

>>[I think the PASC platform being constructed could leverage retrospective and prospective data [particularly with the quick launch that is planned] to address this question].

- What is the feasibility/advisability/utility of including systematic PASC ascertainment questionnaires and mHealth apps (developed by synthesis of PASC consortium/CDD/WHO etc) as part of the vaccine trial post-EUA follow-up assessments and pharmacovigilance?

>>[Perhaps this might be a reasonable collaborative opportunity between PASC/CoVPN/OWS/ACTIV to consider as guided by FDA partners with appropriate buy-in across the ecosystem etc.]

- Once the PASC consortium better establishes an EHR-based 'signature' for PASC (currently lacking an ICD code) - how can we leverage EHR/health systems to track post-vaccine incidence of PASC vs pre-vaccine?

>>[I think the PASC platform being constructed is well poised to address this question].

- Do viral variants differ in their capacity to promote PASC vs the severity of acute COVID-19?

>>[This would obviously require MUCH better and deeper viral variant tracking with broad sampling frame than what I believe we currently have in the US -- [obviously defer to Tony/NIAID/CDC on this]]

- Should PASC endpoints be included in some of the 'early phase', preventive, prophylactic protocols (eg ACTIV2; early Mab; ? interferon; nasal delivery anti-virals)?

>>[Perhaps this might be a reasonable collaborative opportunity between PASC/ACTIV to consider as guided by FDA partners with appropriate buy-in across the ecosystem etc.]

Just a few quick thoughts; clearly worthy of a deeper dive and dialogue with SMEs at some point as PASC gets stood up very soon.

Possible Action Option: Please let us know if you want us to prepare a brief, executive summary description of PASC for ACTIV leadership like b6, if you think that would be helpful.

(BTW, I've found the last couple of ACTIV leadership meeting to be particularly robust and highly engaging dialogues focused on collective solution-discovery to real-time, real-world learning/challenges that arise for the ecosystem vs the conventional WG 'report-out' structure).

Best

Gary

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] b6

Sent: Thursday, March 18, 2021 12:21 PM

To: Patterson, Amy (NIH/NHLBI) [E] b6; Gibbons, Gary (NIH/NHLBI) [E] b6;

Koroshetz, Walter (NIH/NINDS) [E] b6 >; Fauci, Anthony (NIH/NIAID) [E] < b6
Subject: FW: Message

Follow up from b6 based on a brief discussion of PASC at the ACTIV Leadership Team meeting just now.

FC

-----Original Message-----

From b6 b6
Sent: Thursday, March 18, 2021 12:18 PM
To: Collins, Francis (NIH/OD) [E] < b6
Subject: Message

Great ACTIV meeting

The comment from you on preventing long Covid w it's health burden chronically will require that one prevents infections in addition to severe disease as it's an outcome from asymptomatic

I am keen to get connected to those at NIH that deals w long Covid science

May set new goals for how we should think about vaccinations to prevent long Covid as an endpoint and also possibly about which early treatment interventions can reduce long Covid ..

Best
b6

Sent from my iPhone

From: Burklow, John (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2E57F267323B43C08BE856ACB5B964CA-BURKLOWJ]
Sent: 3/18/2021 10:21:54 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Pfizer request: Oral protease inhibitor communications

Flag: Follow up

Hi, Francis—

Actually, yes, we have some concerns. Happy to discuss.

John

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, March 18, 2021 4:48 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Myles, Renate (NIH/OD) [E] <[REDACTED]> b6 Burklow, John (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: Pfizer request: Oral protease inhibitor communications

Any concerns?

From: [REDACTED] b6 [REDACTED] b6
Sent: Thursday, March 18, 2021 4:24 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: [REDACTED] b6 [REDACTED] b6
Subject: Pfizer request: Oral protease inhibitor communications

Dear Dr. Collins,

I am reaching out to you on behalf of [REDACTED] b6 Pfizer plans to issue a press release next Tuesday to announce the start of a Phase 1 trial for our oral protease inhibitor.

We'd like to mention that both the oral and the IV protease programs have conditional acceptance to move forward as part of the ACTIV-2 and the ACTIV-3 clinical trials, if you are open to us doing so. Since the details of the collaborations are under discussion, we have kept the language conditional, yet optimistic.

If you agree with the above, we'd then like to inquire if you'd be willing to provide a quote for the press release related to the ACTIV program. If so, I am happy to coordinate with your communications team.

Thank you for your consideration.

Regards,

COLL0000013030

(b) (6)



From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 3/18/2021 10:57:34 PM
To: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: Re: Pfizer request: Oral protease inhibitor communications

As do I
Larry

On Mar 18, 2021, at 6:21 PM, Burklow, John (NIH/OD) [E] <[REDACTED]> wrote:

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To: Wholley, David (FNIH) [T] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> Myles, Renate (NIH/OD) [E] <[REDACTED]>
Burklow, John (NIH/OD) [E] <[REDACTED]>
Subject: FW: Pfizer request: Oral protease inhibitor communications

Any concerns?

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Cc: [REDACTED]
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Thank you for your consideration.

Regards.

b6



<image002.png>

From: [REDACTED] b6 [REDACTED] b6
Sent: 3/20/2021 5:56:18 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Mammen, Mathai [JJCUS] [REDACTED] b6 Pangalos, Mene [REDACTED] b6 Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Prof Trevor M Jones CBE FMedSci [REDACTED] b6 Stoffels, Paul [REDACTED] b6
Subject: Re: [EXTERNAL] Hever yesterday
Flag: Follow up

Dear Francis and colleagues

I am sure Francis shared the slide with the best intention. A very similar slide (or identical) was discussed at ACTIV SC, as you reminded us, and perceived by everyone as a helpful piece in the puzzle of elucidating immune protection against SARS-CoV2.

Neutralizing antibodies are important in viral immune therapy while binding non-neutralized are in general seen as having mixed value. They may be associated with harmful or beneficial effects in various patients and therefore often taken with caution. The topic didn't seem to be embraced as a priority currently among the ACTIV participants in the last meeting.

The role of SARS-CoV2 specific T cells (eg CD8 T) was discussed as an important adjunct factor, particularly when levels neutralizing Abs are low.

It would be great if one can develop standardized simple assays for measuring SARS-CoV2 antigen specific T cells (eg CD8, CD4) and assess in addition to neutralizing antibodies as correlate to protection. It's however a complex task as a functional T cell assay hasn't yet been easily used for guidance in any areas. Maybe it's time to make this happen and we can facilitate this jointly.

Best
[REDACTED] b6

Sent from my iPhone

On Mar 20, 2021, at 13:04, Collins, Francis (NIH/OD) [E] <[REDACTED] b6> wrote:

Hi Mathai and Mene,

Apologies that one slide I showed at the Hever meeting yesterday did not do justice to the best ways to assess the effect of emerging variants on vaccine efficacy. That one slide was derived from a recent presentation by an academic PI (I believe it was David Ho) to the Vaccines Working Group, and I should not have presented it as if it were a product of the ACTIV team

working on the TRACE program. The members of the TRACE subgroup have avoided making side by side comparisons of efficacy estimates and IC50s, in order to avoid such confusion. JnJ and AZ have been involved in this TRACE plan, for which we are grateful.

With respect to what appears to be an exclusive focus on neutralizing Abs, we agree it is time to assess how to include binding Abs and T-cell effects, for both in vitro and in vivo studies. The TRACE team (Joe Menetski is the lead organizer) would be grateful for your thoughts on this.

Best, Francis

From: Mammen, Mathai [JJCUS] [b6]
Sent: 3/20/2021 7:28:29 PM
To: b6 b6
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Pangalos, Mene [b6 Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Prof Trevor M Jones CBE FMedSci [b6 Stoffels, Paul [JJCUS] [b6]
Subject: Re: Hever yesterday
Flag: Follow up

Fully agree, b6 on all counts. I do think it is time for us to think thought robust T cell assays that are broadly useful for the industry. Janssen stands ready to help in whatever way appropriate.
Mathai

Sent from my iPhone

On Mar 20, 2021, at 1:56 PM, b6 b6 wrote:

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b6

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From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-AFAUCI]
Sent: 3/20/2021 8:11:38 PM
To: Koroshetz, Walter (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8338dd7cdcd432e986961f1548c5ec6-koroshetzw]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Message

Persistence of latent virus is certainly a possibility. We have seen that on several occasions with Ebola after full recovery of the patient.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520
Phone: b6
FAX: (301) 496-4409
E-mail: b6

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From: Koroshetz, Walter (NIH/NINDS) [E] <b6>
Sent: Thursday, March 18, 2021 4:15 PM
To: Collins, Francis (NIH/OD) [E] <b6> Gibbons, Gary (NIH/NHLBI) [E] <b6>
Patterson, Amy (NIH/NHLBI) [E] <b6> Fauci, Anthony (NIH/NIAID) [E] <b6>
Cc: Wholley, David (FNIH) [T] <b6>
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From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Thursday, March 18, 2021 4:11 PM
To: Gibbons, Gary (NIH/NHLBI) [E] <b6> Patterson, Amy (NIH/NHLBI) [E] <b6>
Koroshetz, Walter (NIH/NINDS) [E] <b6> Fauci, Anthony (NIH/NIAID) [E] <b6>

Cc: Wholley, David (FNIH) [T] b6

Subject: RE: Message

Hi Gary,

I agree the last couple of ACTIV Leadership Meetings have been very significant, and this conversation about PASC – albeit brief – is good example. Your list is good. One other item to add – there are now anecdotal reports of individuals suffering from PASC months after natural infection with COVID-19, who say they had a dramatic recovery after vaccination. Probably that's not going to be a widespread phenomenon, but it should certainly be tracked.

Yes, a brief executive summary of PASC for ACTIV would be useful. I'm looping in David Wholley.

Francis

From: Gibbons, Gary (NIH/NHLBI) [E] b6

Sent: Thursday, March 18, 2021 2:17 PM

To: Collins, Francis (NIH/OD) [E] <b6> Patterson, Amy (NIH/NHLBI) [E] b6

Koroshetz, Walter (NIH/NINDS) [E] b6 Fauci, Anthony (NIH/NIAID) [E] b6

Subject: RE: Message

Hi Francis,

Thanks for sharing this ACTIV meeting follow-up query.

The team will need to give this further brainstorming/dialogue; but in short, I suspect we can all agree that b6 basic premise/hypothesis is quite plausible and worthy of testing.

A few quick, first-pass considerations come to mind:

- What is the clinical spectrum and natural history of SARS-CoV2 **RE-infection** in patients with PASC compared to non-PASC/COVID-positive comparator controls in the NIH SARS-CoV2 Recovery Meta-Cohort?
- How can we best leverage the well phenotyped participants in the SARS-CoV2 Recovery Meta-Cohort to better understand the clinical/sub-clinical consequences of *re-infection* by original or new variants?

>>[I think the PASC platform being constructed could be well poised to address this question].

- Are there differences in the incidence/prevalence of PASC in the pre-vaccine phase of the pandemic vs the 'post-vaccine' phase of the pandemic?

>>[I think the PASC platform being constructed could leverage retrospective and prospective data [particularly with the quick launch that is planned] to address this question].

- What is the feasibility/advisability/utility of including systematic PASC ascertainment questionnaires and mHealth apps (developed by synthesis of PASC consortium/CDD/WHO etc) as part of the vaccine trial post-EUA follow-up assessments and pharmacovigilance?

>>[Perhaps this might be a reasonable collaborative opportunity between PASC/CoVPN/OWS/ACTIV to consider as guided by FDA partners with appropriate buy-in across the ecosystem etc.]

- Once the PASC consortium better establishes an EHR-based 'signature' for PASC (currently lacking an ICD code) - how can we leverage EHR/health systems to track post-vaccine incidence of PASC vs pre-vaccine?

>>[I think the PASC platform being constructed is well poised to address this question].

- Do viral variants differ in their capacity to promote PASC vs the severity of acute COVID-19?

>>[This would obviously require MUCH better and deeper viral variant tracking with broad sampling frame than what I believe we currently have in the US -- [obviously defer to Tony/NIAID/CDC on this]]

- Should PASC endpoints be included in some of the 'early phase', preventive, prophylactic protocols (eg ACTIV2; early Mab; ? interferon; nasal delivery anti-virals)?

>>[Perhaps this might be a reasonable collaborative opportunity between PASC/ACTIV to consider as guided by FDA partners with appropriate buy-in across the ecosystem etc.]

Just a few quick thoughts; clearly worthy of a deeper dive and dialogue with SMEs at some point as PASC gets stood up very soon.

Possible Action Option: Please let us know if you want us to prepare a brief, executive summary description of PASC for ACTIV leadership like [b6] if you think that would be helpful.

(BTW, I've found the last couple of ACTIV leadership meeting to be particularly robust and highly engaging dialogues focused on collective solution-discovery to real-time, real-world learning/challenges that arise for the ecosystem vs the conventional WG 'report-out' structure).

Best

Gary

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6] >

Sent: Thursday, March 18, 2021 12:21 PM

To: Patterson, Amy (NIH/NHLBI) [E] [b6] Gibbons, Gary (NIH/NHLBI) [E] [b6]

Koroshetz, Walter (NIH/NINDS) [E] <[b6]>; Fauci, Anthony (NIH/NIAID) [b6]

Subject: FW: Message

Follow up from [b6] based on a brief discussion of PASC at the ACTIV Leadership Team meeting just now.

FC

-----Original Message-----

From: [b6] [b6]

Sent: Thursday, March 18, 2021 12:18 PM

To: Collins, Francis (NIH/OD) [E] <[b6]>

Subject: Message

Great ACTIV meeting

The comment from you on preventing long Covid w it's health burden chronically will require that one prevents infections in addition to severe disease as it's an outcome from asymptomatic

I am keen to get connected to those at NIH that deals w long Covid science

May set new goals for how we should think about vaccinations to prevent long Covid as an endpoint and also possibly about which early treatment interventions can reduce long Covid ..

Best

[b6]

Sent from my iPhone

From: [b6] [b6]
Sent: 3/20/2021 8:36:46 PM
To: Mammen, Mathai [JJCUS] [b6]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Pangalos, Mene [mene.panga [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Prof Trevor M Jones CBE FMedSci [b6] Stoffels, Paul [JJCUS] [b6]
Subject: Re: [EXTERNAL] Re: Hever yesterday
Flag: Follow up

Maybe ACTIV can lead as we have all of us including FDA there ..

Sent from my iPhone

On Mar 20, 2021, at 15:28, Mammen, Mathai [JJCUS] <[b6]> wrote:

Fully agree, [b6] on all counts. I do think it is time for us to think thought robust T cell assays that are broadly useful for the industry. Janssen stands ready to help in whatever way appropriate.

Mathai

Sent from my iPhone

On Mar 20, 2021, at 1:56 PM, [b6] [b6] wrote:

Dear Francis and colleagues

I am sure Francis shared the slide with the best intention. A very similar slide (or identical) was discussed at ACTIV SC, as you reminded us, and perceived by everyone as a helpful piece in the puzzle of elucidating immune protection against SARSCov2.

Neutralizing antibodies are important in viral immune therapy while binding non-neutralized are in general seen as having mixed value. They may be associated with harmful or beneficial effects in various patients and therefore often taken with caution. The topic didn't seem to be embraced as a priority currently among the ACTIV participants in the last meeting.

The role of SARSCov2 specific T cells (eg CD8 T) was discussed as an important adjunct factor, particularly when levels neutralizing Abs are low.

It would be great if one can develop standardized simple assays for measuring SARS-CoV2 antigen specific T cells (eg CD8, CD4) and assess in addition to neutralizing antibodies as correlate to protection . It's however a complex task as a functional T cell assay hasn't yet been easily use for guidance in any areas . Maybe it's time to make this happen and we can facilitate this jointly .

Best
b6

Sent from my iPhone

On Mar 20, 2021, at 13:04, Collins, Francis (NIH/OD) [E]

b6 > wrote:

Hi Mathai and Mene,

Apologies that one slide I showed at the Hever meeting yesterday did not do justice to the best ways to assess the effect of emerging variants on vaccine efficacy. That one slide was derived from a recent presentation by an academic PI (I believe it was David Ho) to the Vaccines Working Group, and I should not have presented it as if it were a product of the ACTIV team working on the TRACE program. The members of the TRACE subgroup have avoided making side by side comparisons of efficacy estimates and IC50s, in order to avoid such confusion. JnJ and AZ have been involved in this TRACE plan, for which we are grateful.

With respect to what appears to be an exclusive focus on neutralizing Abs, we agree it is time to assess how to include binding Abs and T-cell effects, for both in vitro and in vivo studies. The TRACE team (Joe Menetski is the lead organizer) would be grateful for your thoughts on this.

Best, Francis

From: Trevor Jones [b6]
Sent: 3/20/2021 10:10:19 PM
To: b6 b6
CC: Mammen, Mathai [JJCUS] [b6] Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Pangalos, Mene [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stoffels, Paul [JJCUS] [b6]
Subject: Re: [EXTERNAL] Re: Hever yesterday

Agree
I will propose that

Sent from my iPhone

On 20 Mar 2021, at 20:36, b6 b6 wrote:

Maybe ACTIV can lead as we have all of us including FDA there ..

Sent from my iPhone

On Mar 20, 2021, at 15:28, Mammen, Mathai [JJCUS] < b6 >
wrote:

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Sent from my iPhone

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Neutralizing antibodies are important in viral immune therapy while binding non-neutralized are in general seen as having mixed value . They may be associated w harmful or beneficial effects in various patients and therefore often taken w caution. The topic didn't seem to be embraced as a priority currently among the ACTIV participants in the last meeting .

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Best
b6

Sent from my iPhone

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(NIH/OD) [E] < b6 > wrote:

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With respect to what appears to be an exclusive focus on neutralizing Abs, we agree it is time to assess how to include binding Abs and T-cell effects, for both in vitro and in vivo studies. The

TRACE team (Joe Menetski is the lead organizer)
would be grateful for your thoughts on this.

Best, Francis

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [b6]
Sent: 1/17/2021 5:56:10 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]
Subject: RE: GISAID and data access limitations

Francis,

Also look forward to working with you on the big tasks ahead with variant viruses. Regarding GISAID, this is a complicated issue as you've pointed out. The database was stood up in 2008 for H5N1, but has been the primary repository for seasonal and novel influenza globally since that time. It is the recommended repository for influenza from WHO. The same was done for SARS-CoV-2. GISAID was stood up in an attempt to address significant problems that many nations were concerned about, including attribution of their work in subsequent publications and the use of their genetic sequence data in research and development. For this reason, the data use agreement reflects restrictions on the subsequent use of the data, and limits access to parties not agreeing to the data use agreement. Dave Wentworth serves on the Scientific Advisory Committee which works to improve accuracy and fidelity of the influenza sequences; however, that committee has not addressed the broader more fundamental issue you raise.

There are many aspects of GISAID that would benefit from improvement, both technical and, as you point out here, policy. To address changes to the existing GISAID DUA would require addressing the larger issue that many countries see as a protection of their work. Because of the multilateral participants in the issue, and with the strong connection to parts of WHO, CDC has been addressing GISAID policy issues through the HHS Office of Global Affairs and Department of State through Jonathon Margolis' office.

I agree with you that we really need a better global sequencing solution, but given the timing of transition and the thaw in relationships with WHO, I would recommend putting the GISAID access policy issues into the broader ongoing discussion of USG's near-term strategic discussions with WHO and other global partners. To change the data use policy will require other nations to communicate the same message and solutions. Happy to have a further discussion if that would be useful.

Thanks

Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office [b6] Cell [b6]
[b6], www.cdc.gov/fiu

From: Collins, Francis (NIH/OD) [E] < [b6] >
Sent: Saturday, January 16, 2021 8:44 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < [b6] >
Cc: Menetski, Joseph (FNIH) [T] < [b6] > Tabak, Lawrence (NIH/OD) [E] < [b6] >

COLL0000013078

Subject: GISAID and data access limitations

Dear Dan,

Thanks very much for the opportunity to work with you and CDC on the increasingly serious issue of mutations in SARS-CoV-2 that might affect the efficacy of vaccines and monoclonal antibodies.

I wanted to ask your advice about the GISAID database. I know this was originally developed during the H5N1 influenza outbreak. GISAID then stepped forward in 2020 to make its capabilities available in the context of the threats from SARS-CoV-2. That was a good thing, but unfortunately I understand that GISAID strictly limits access to data. This will block some of the plans for the new NCBI database the ACTIV project is proposing, and seems like the wrong model in the midst of a global pandemic.

I hope the GISAID leadership might be willing to reconsider this policy. Is this something that you have already approached? I would think the CDC SPHERES project would be particularly interested in encouraging open access across the world for this kind of data, especially with the rapid emergence of new SARS-CoV-2 variants that may have major significance. From the web, I see that David Wentworth of CDC is on the GISAID Scientific Advisory Committee, could he help make this case?

On behalf of NIH (including NCBI/NLM and NIAID) I am flagging this as an important issue. I would like to work with CDC in seeking a more open approach by GISAID. I would bet that Rochelle Walensky would also support this. Can I get your advice on how this might be best approached?

Thanks for your help,

Francis

From: Rutter, Joni (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=157B2517DDB546A8A72844C35EADB062-JRUTTER]
Sent: 3/23/2021 1:15:27 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: question about viral isolates chosen for sequencing

Hi Francis,
Closing the loop here; Emily is setting up a meeting with the CDC folks to follow up.

Joni

From: Erbeling, Emily (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Monday, March 22, 2021 1:00 PM
To: Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> b6
Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <[REDACTED]> b6; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> b6; Dugan, Vivien (CDC/DDID/NCIRD/ID) <[REDACTED]> b6; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <[REDACTED]> b6; Herrod, Lisa (NIH/NIAID) [C] <[REDACTED]> b6
Subject: FW: question about viral isolates chosen for sequencing

Dear Joni,
See the conversation below between Francis and some of our CDC colleagues.
I will ask my assistant Lisa to schedule a 30 minute meeting to include Tom Clark, you, myself and any of the CDC colleagues that Tom designates.

The purpose will be to review current plans for collecting sequence data on vaccine breakthroughs, as well as available demographics on US based sequences samples.

Lisa: OK to schedule this any time that it fits will the parties listed above (no big rush).
Thanks all.
Emily

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, March 22, 2021 11:43 AM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <[REDACTED]> b6; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> b6
Cc: Dugan, Vivien (CDC/DDID/NCIRD/ID) <[REDACTED]> b6; Galloway, Summer (CDC/DDID/NCIRD/ID) <[REDACTED]> b6; Erbeling, Emily (NIH/NIAID) [E] <[REDACTED]> b6; Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> b6; Wholley, David (FNIH) [T] <[REDACTED]> b6; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6; Freire, Maria (FNIH) [T] <[REDACTED]> b6; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6; Anderson, James (NIH/OD) [E] <[REDACTED]> b6; Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6; Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]> b6
Subject: RE: question about viral isolates chosen for sequencing

Hi Nancy,

New York might be a factor, but the main driver in the ACTIV discussion was the argument for vigilance for whatever comes next that might be even less responsive to existing vaccines than B.1.526 or B.1.351. And if

you were going to go looking for that, sequencing the virus in vaccine breakthroughs would seem to be a good idea.

The ACTIV Leadership Team also raised questions about whether viral isolates are being sequenced from underserved groups. I've asked Joni Rutter to follow up with you and Dan about that.

Many thanks, Francis

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [REDACTED] b6
Sent: Monday, March 22, 2021 7:32 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED] b6>; Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Dugan, Vivien (CDC/DDID/NCIRD/ID) <[REDACTED] b6>; Galloway, Summer (CDC/DDID/NCIRD/ID) [REDACTED] b6; Erbelding, Emily (NIH/NIAID) [E] [REDACTED] b6 >
Subject: RE: question about viral isolates chosen for sequencing

Just to add a bit. We have been in touch with Emily around our breakthrough cases, including sending the one-pager on breakthrough investigations. David Kessler has already reached out to CDC, OWS, ASPR and NIH about serology for breakthrough cases and, I think, had asked Robert Johnson to organize a call about that. Is this conversation coming up again because of NYC as there seem to be multiple conversations related to that. If so, our state and local team is working with them on their investigations.

Nancy

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [REDACTED] b6
Sent: Sunday, March 21, 2021 10:11 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <[REDACTED] b6>; Dugan, Vivien (CDC/DDID/NCIRD/ID) [REDACTED] b6; Galloway, Summer (CDC/DDID/NCIRD/ID) <[REDACTED] b6>
Subject: RE: question about viral isolates chosen for sequencing

Francis:

Thanks. Regarding sequencing of variants, yes, priority will be given to any specimen/virus available. I have cc'd Vivien Dugan who can address the efforts, and the challenges in getting available specimen after the initial testing is done.

There is a specific effort on facilitating evaluation of these cases. Nancy is cc'd and can respond and connect folks from the Vaccine Task Force that are working on studies and surveillance to address what you have identified. I have attached a slide deck from a NSC briefing the SIG gave on Friday which addresses this in the vaccine section around slide 20. There is a table with the various activities. Let us know if this answers the question and happy to work with Nancy on follow ups.

Thanks

Dan.

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Sunday, March 21, 2021 9:15 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED] b6>
Cc: Messonnier, Nancy (CDC/DDID/NCIRD/OD) <[REDACTED] b6>
Subject: question about viral isolates chosen for sequencing

Hi Dan,

A question came up at the ACTIV leadership team meeting last week that I wasn't able to answer. In CDC's surveillance of viral genome sequencing, is special priority being placed on isolates from individuals who developed COVID-19 after vaccination (the "breakthroughs")? Those samples would of course be of special interest and concern, since they might represent new and more resistant variants that we would want to know about. I know some of the states seem to be prioritizing these samples, but is that something that CDC is directing across the country?

Thanks, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/23/2021 8:57:52 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021
Attachments: 210323 - Lessons Learned Initiative - Leadership Meeting_vShare.pptx; 210323 - Tx Lessons Learned Initiative - Fact Base_vShare.docx

Flag: Follow up

Sharing the USG Tx Lessons Learned recommendations for review with the war room – happy to collect any feedback on these to share with Kevin and the group before the next follow up meeting early next week.

David – you may have seen these already given Mike and Stacey are involved with the ACTIV/NIH WG and PM teams respectively.

Thanks,
Ashley

From: Bugin, Kevin <[REDACTED]> b6
Sent: Monday, March 22, 2021 1:04 PM
To: Woodcock, Janet (FDA/OC) [REDACTED] b6; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [REDACTED] b6; Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Armstrong, Kimberly (OS/ASPR/BARDA) [REDACTED] b6; Adam, Stacey (FNIH) [T] [REDACTED] b6; Victoria Davey <[REDACTED]> b6; Kilgore, Nicole R CIV USARMY (USA) [REDACTED] b6; 'jason.w.roos.civ@mail.mil' [REDACTED] b6
Cc: Teyhen, Deydre (HHS/IOS) <[REDACTED]> b6; Erhardt, Bill (NIH/NIAID) [C] [REDACTED] b6; Stone, Jessica [REDACTED] b6; Tarnita, Roxana [REDACTED] b6; King, Mason [REDACTED] b6; Kristin Schneeman [REDACTED] b6; 'Esther Krofah' [REDACTED] b6; 'Dr Mark McClellan, M.D.' [REDACTED] b6; 'Morgan Romine' [REDACTED] b6; [REDACTED] b6; Santos, Michael (FNIH) [T] [REDACTED] b6 >
Subject: [Pre-read] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Good afternoon,

Hope you are having a great start to your week and thank you again for helping steer the USG's Covid-19 Clinical Evaluation of Therapeutics Lessons Learned effort.

COLL0000013129

Over the past few weeks, together with numerous partners across the clinical research landscape who have worked together in Working Groups, we have compiled a broad array of lessons learned and have distilled these into select action-oriented recommendations that we are hoping to discuss with you tomorrow. We look forward to your review and guidance on which of these recommendations to pursue further as part of the next phase of the effort, which is focused on building detailed action plans to address the recommendations.

Ahead of the discussion, please find attached a pre-read of the materials we will be reviewing. We are aiming to spend the majority of the time tomorrow discussing the synthesized recommendations on slides 9-15. Additional information on recommendation development methodology and a more detailed set of recommendations from each of the Working Groups can be found on pages 19-23 and 25-41, respectively. If you are able to review these materials ahead of tomorrow, it will provide the opportunity for a much richer discussion and would be greatly appreciated.

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Thank you and please don't hesitate to reach out with any questions. Looking forward to the discussion.

Best,
Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6] >

Sent: Wednesday, February 10, 2021 1:53 PM

To: Woodcock, Janet; Ramakrishnan, Raahul; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Armstrong, Kimberly (OS); Adam, Stacey J (NIH); [b6] Kilgore, Nicole R CIV USARMY (USA);

[b6] Kristin Schneeman; 'Esther Krofah'; 'Dr Mark McClellan, M.D.'; 'Morgan Romine';

[b6] Santos, Michael R (NIH)

Cc: Teyhen, Deydre (OS); Erhardt, Bill A (NIH)

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point

When: Tuesday, March 23, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Review progress of small working groups to kick-off and collate fact-base, approve prioritization from small working groups, and provide guidance on path to synthesis and public dissemination.

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Join by phone

<input type="text" value="b6"/>	US Toll
<input type="text" value="b6"/>	US Toll Free

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/23/2021 7:32:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021
Attachments: 210323 - Lessons Learned Initiative - Leadership Meeting_vShare.pptx; 210323 - Tx Lessons Learned Initiative - Fact Base_vShare.docx

Hi Francis,

The USG Tx Lessons Learned leadership team met for the second meeting today to discuss recommendations put forth by the WGs. Attached are the slides with recommendations and a fact base document to support the prioritized list.

We were able to cover the background and slides 9-12 with recommendations for the first 4 major themes and plan to discuss the others during a follow-up meeting. In summary, there is collective agreement regarding approving the recommendations. You will notice some of the recommendations (1.1, 1.2, 1.4, 2.2) were stood up by OWS/ACTIV/NIH to address COVID but Janet has stressed the need to have some form of legislation behind them to determine who is responsible/in-charge for future pandemics. I was hoping potential leads would have been identified for the recommendations (but maybe this needs further discussion) however there is a list of stakeholders for each.

As you know Stacey (USG Tx PM team) and Mike (leading ACTIV/NIH WG recs/actions) are also involved with these conversations.

I will follow up after we complete review of the remaining recommendations and happy to share any thoughts you may have.

Thanks,
Ashley

From: Bugin, Kevin <[REDACTED]>
Sent: Monday, March 22, 2021 1:04 PM
To: Woodcock, Janet (FDA/OC) <[REDACTED]> Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[REDACTED]> Parker, Ashley (NIH/OD) [E] <[REDACTED]> Armstrong, Kimberly (OS/ASPR/BARDA) <[REDACTED]> Adam, Stacey (FNIH) [T] <[REDACTED]> Victoria Davey <[REDACTED]> Kilgore, Nicole R CIV USARMY (USA) <[REDACTED]> [REDACTED] <[REDACTED]>
Cc: Teyhen, Deydre (HHS/IOS) <[REDACTED]> Erhardt, Bill (NIH/NIAID) [C] <[REDACTED]> Stone, Jessica <[REDACTED]> Tarnita, Roxana <[REDACTED]> King, Mason <[REDACTED]> Kristin Schneeman <[REDACTED]> 'Esther Krofah' <[REDACTED]> 'Dr Mark McClellan, M.D.' <[REDACTED]> 'Morgan Romine' <[REDACTED]> [REDACTED] <[REDACTED]> Santos, Michael (FNIH) [T] <[REDACTED]>
Subject: [Pre-read] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Good afternoon,

Hope you are having a great start to your week and thank you again for helping steer the USG's Covid-19 Clinical Evaluation of Therapeutics Lessons Learned effort.

COLL0000013132

Over the past few weeks, together with numerous partners across the clinical research landscape who have worked together in Working Groups, we have compiled a broad array of lessons learned and have distilled these into select action-oriented recommendations that we are hoping to discuss with you tomorrow. We look forward to your review and guidance on which of these recommendations to pursue further as part of the next phase of the effort, which is focused on building detailed action plans to address the recommendations.

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Cc: Teyhen, Deydre (OS); Erhardt, Bill A (NIH)
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When: Tuesday, March 23, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
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Join by phone

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/23/2021 9:13:43 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

No, Ashley, this is the first I have seen of them. Version control, I imagine. Anyway, thanks for sending.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, March 23, 2021 4:58 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> Anderson, James (NIH/OD) [E] <[REDACTED]> Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Sharing the USG Tx Lessons Learned recommendations for review with the war room – happy to collect any feedback on these to share with Kevin and the group before the next follow up meeting early next week.

David – you may have seen these already given Mike and Stacey are involved with the ACTIV/NIH WG and PM teams respectively.

Thanks,
Ashley

From: Bugin, Kevin [REDACTED]
Sent: Monday, March 22, 2021 1:04 PM
To: Woodcock, Janet (FDA/OC) <[REDACTED]>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Armstrong, Kimberly (OS/ASPR/BARDA) <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Victoria Davey <[REDACTED]>; Kilgore, Nicole R CIV USARMY (USA) <[REDACTED]>; [REDACTED]
Cc: Teyhen, Deydre (HHS/IOS) <[REDACTED]>; Erhardt, Bill (NIH/NIAID) [C] <[REDACTED]>; Stone, Jessica <[REDACTED]>; Tarnita, Roxana <[REDACTED]>; King, Mason <[REDACTED]>; Kristin Schneeman <[REDACTED]>; 'Esther Krofah' <[REDACTED]>; 'Dr Mark McClellan, M.D.' <[REDACTED]>; 'Morgan Romine' <[REDACTED]>

COLL0000013135

b6 b6 >; Santos, Michael (FNIH) [T] b6
Subject: [Pre-read] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

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Sent: Wednesday, February 10, 2021 1:53 PM
To: Woodcock, Janet; Ramakrishnan, Raahul; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Armstrong, Kimberly (OS); Adam, Stacey J (NIH); b6; Kilgore, Nicole R CIV USARMY (USA);
' b6 Kristin Schneeman; 'Esther Krofah'; 'Dr Mark McClellan, M.D.'; 'Morgan Romine';
' b6 Santos, Michael R (NIH)
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From: [b6]
Sent: 3/26/2021 4:59:22 PM
To: Bradner, James [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] BGTC

Flag: Follow up

Jay

I and [b6] (b) (4)

I ask David Wholley provide you w details

On [b6] (b) (4)

Lessons learned [b6] (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James <[b6]> wrote:

thanks, [b6]

[b6] (b) (4)

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[b6] | @jaybradner

COLL0000013168

<image001.jpg>

From: b6 <b6>
Date: Friday, March 26, 2021 at 10:56 AM
To: James Bradner <b6>
Subject: Re: [EXTERNAL] BGTC

Thanks Jay
Hope all is well w you
What's status for your PI program ?

Yes - we are advancing w NIH, FDA a gene therapy consortia and have many companies joining

We are champs w CBER

Do you , NOV want to join - would be fabulous

Sent from my iPhone

On Mar 26, 2021, at 10:31, Bradner, James <b6> wrote:

b6 - congratulations on all the truly remarkable work at pfizer, and the transition of the oral protease inhibitor to human clinical investigation. admist all the important and timely discussions about pandemic preparedness, the thread on gene therapies and the PPP therein (BGTC i believe) has gone quiet. is there still momentum there? who is the champion? thanks so much, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

<image001.jpg>

From: Bradner, James [REDACTED] b6
Sent: 3/26/2021 5:19:57 PM
To: [REDACTED] b6 [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] BGTC

thank you, [REDACTED] b6 , for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated the [REDACTED] (b) (4) this will surely be a good move to [REDACTED] (b) (4) . as such, the discovery and early [REDACTED] (b) (4) will now be led by my leadership team at NIBR. so i am getting up to speed on partnerships and collaborations.

could i put upon an NIH leader to meet and discuss the status of BGTC, [REDACTED] (b) (4) , and i am hopeful they will remain as closely connected to this rising opportunity to work together as before.

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] b6 | @jaybradner

**BLACK
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MATTER**



From: [REDACTED] b6 [REDACTED] b6
Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner <[REDACTED] b6>
Cc: David Wholley <[REDACTED] b6> "Collins Francis [E]" <[REDACTED] b6>
Subject: Re: [EXTERNAL] BGTC

Jay

I and [REDACTED] (b) (4)

I ask David Wholley provide you w details

On the [REDACTED] (b) (4)

Lessons learned on [REDACTED] (b) (4)

Sent from my iPhone

COLL0000013169

On Mar 26, 2021, at 12:30, Bradner, James <[REDACTED]> wrote:

thanks, [REDACTED]

(b) (4)



best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] | @jaybradner

From: [b6]
Sent: 3/26/2021 7:01:32 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Bradner, James [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]
Subject: Re: [EXTERNAL] BGTC

Jay
Pls review fast
This is an unique opportunity to make remarkable impact on patient w curative intent as a team while advancing the field for the benefit of everyone as a scientist
Hope to see you in our team soon formally

[b6]

On Mar 26, 2021, at 2:57 PM, Wholley, David (FNIH) [T] <[b6]> wrote:

Jay,
Great to hear you are taking the reins on this. We have been working for the last 9 months or so on developing a plan (attached) with participation from several NIH Institutes, Peter Marks from FDA, and 12-13 companies, including Novartis. The Novartis reps are Sam Yaghmour and Scott Galasinski; both have been instrumental in providing expertise and insight throughout the concept and plan development process.

We are happy to involve you or others on your team in this and bring whomever you designate up to speed with a briefing asap. We are at point of seeking final approvals and financial commitments from private sector partners with a plan to launch something this summer, so your note is timely. I am copying Steve Hoffmann and Joe Menetski on my team who have been managing this effort. Please let us know with whom you would like us to follow up.

Looking forward to your support and active involvement in the AMP BGTC program.

David

From: Bradner, James <[b6]>
Sent: Friday, March 26, 2021 1:20 PM

COLL0000013175

To: b6
Cc: Wholley, David (FNIH) [T] <b6> Collins, Francis (NIH/OD) [E] <b6>
Subject: Re: [EXTERNAL] BGTC

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Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

<image002.jpg>

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Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner b6 >
Cc: David Wholley b6, "Collins Francis [E]" b6 >
Subject: Re: [EXTERNAL] BGTC

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Sent from my iPhone

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President | Novartis Institutes for BioMedical Research
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<AMP BGTC Research Plan_3.12.2021.pdf>

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/26/2021 6:55:35 PM
To: Bradner, James [b6] [b6] [b6]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]
Subject: RE: [EXTERNAL] BGTC
Attachments: AMP BGTC Research Plan_3.12.2021.pdf

Flag: Follow up

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David

From: Bradner, James < b6 >
Sent: Friday, March 26, 2021 1:20 PM
To: b6 b6
Cc: Wholley, David (FNIH) [T] < b6 > Collins, Francis (NIH/OD) [E] < b6 >
Subject: Re: [EXTERNAL] BGTC

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COLL0000013177

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner b6
Cc: David Wholley b6 "Collins Francis [E]" b6
Subject: Re: [EXTERNAL] BGTC

Jay

I and (b) (4)

I ask David Wholley provide you w details

On (b) (4) we expect soon to be in P2/3 studies for both IV and Oral as we have generated quite some favorable P1b data already

Lessons learned (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James b6 wrote:

thanks, b6

(b) (4)

best, jay

COLL0000013177

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

b6 | @jaybradner

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/29/2021 5:14:25 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Francis, and Larry,

Please see below and provide your guidance, as this is an NIH funding request.

(b) (5)

(b) (5)

Thanks, David

From: Bugin, Kevin <[REDACTED]> b6
Sent: Monday, March 29, 2021 12:38 PM
To: Kim, Peter (NIH/NIAID) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6 Johnson, Martin S. (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Brooks, John (NIH/NIAID) [E] <[REDACTED]> b6 Erhardt, Bill (NIH/NIAID) [C] <[REDACTED]> b6 Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6
Subject: Re: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Did we explore the other options ? If so, and the answer was those other options will not work, then let's put it on the tracker and try to push it. We'll need to brief Dina and solicit her help in making the request. This is beyond the remit of Janet and I.

Kevin

From: Johnson, Martin S. (NIH/NIAID) [E] [REDACTED] b6
Sent: Monday, March 29, 2021 11:45:01 AM
To: Kim, Peter S (NIH) [REDACTED] b6 >; Bugin, Kevin [REDACTED] b6 >; Wholley, David N (NIH) <[REDACTED]> b6
Cc: Lane, Henry C (NIH) <[REDACTED]> b6 ; Brooks, John C (NIH) <[REDACTED]> b6 Erhardt, Bill A (NIH) <[REDACTED]> b6 >; Read, Sarah W (NIH) [REDACTED] b6
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Kevin,

(b) (5)

COLL0000013183

Thanks

From: Kim, Peter (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Thursday, March 18, 2021 11:33 AM
To: Bugin, Kevin (FDA/CDER) [REDACTED] b6; Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6; Johnson, Martin S. (NIH/NIAID) [E] [REDACTED] b6
Brooks, John (NIH/NIAID) [E] [REDACTED] b6; Erhardt, Bill (NIH/NIAID) [C] [REDACTED] b6; Read, Sarah (NIH/NIAID) [E] [REDACTED] b6
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi Kevin, David,

(b) (5)

(b) (5)

please let

me know. Also happy to undertake further discussion as needed.

Thanks,

Peter

From: Bugin, Kevin [REDACTED] b6
Sent: Wednesday, March 17, 2021 7:25 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Kim, Peter (NIH/NIAID) [E] [REDACTED] b6; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6; Johnson, Martin S. (NIH/NIAID) [E] [REDACTED] b6
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

COLL0000013183

Hi David,

Looping in Martin Johnson.

So, my understanding is that

(b) (5)

(b) (5)

I guess two points for Dr. Collins:

1.

(b) (5)

2.

Hope this is helpful!

Kevin

From: Wholley, David (FNIH) [T] b6 >

Sent: Wednesday, March 17, 2021 6:43 PM

To: Bugin, Kevin b6

Cc: Kim, Peter S (NIH) < b6 Lane, Henry C (NIH) b6

Subject: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

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Hi Kevin—

Francis has agreed to help push this as a priority. He's asked who you've spoken with so far about this and who actually ultimately approves it (he's guessing David Kessler but wanted to make sure). Also, Peter, is there any kind of estimate of what NIAID would need to do this? Thanks, David

David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

b6 | fniih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852



COLL0000013183

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/29/2021 5:17:08 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: [EXTERNAL] BGTC
Flag: Follow up

5:30 is fine—the last part of these meetings is rarely that informative, and Stacey will be on the call anyway. Whatever works for Joe and/or Steve is fine with me. Cheryl, can you help get an answer here for us?

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, March 29, 2021 1:12 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Hoffmann, Steve (FNIH) [T] <[REDACTED]> b6; Menetski, Joseph (FNIH) [T] <[REDACTED]> b6; Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] BGTC

Would 6 pm be better for you?

From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Monday, March 29, 2021 1:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Hoffmann, Steve (FNIH) [T] [REDACTED] b6 >; Menetski, Joseph (FNIH) [T] [REDACTED] b6 >; Melencio, Cheryl (FNIH) [T] [REDACTED] b6
Subject: RE: [EXTERNAL] BGTC

Yes, I can miss the last half hour of the USG Therapeutics call. I would like to have either Joe Menetski or Steve Hoffmann join the call, if possible, as they have been working this directly with the companies and can answer any detailed questions.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, March 29, 2021 1:02 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6
Subject: RE: [EXTERNAL] BGTC

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Sent: Monday, March 29, 2021 12:52 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 >
Subject: FW: [EXTERNAL] BGTC

Would you have time at 5 pm to talk with Jay?

From: Bradner, James [REDACTED] b6
Sent: Monday, March 29, 2021 12:16 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 >
Cc: Wholley, David (FNIH) [T] <[REDACTED] b6 >; [REDACTED] b6 [REDACTED] b6 >
Subject: Re: [EXTERNAL] BGTC

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Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] b6 | @jaybradner

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From: "Collins, Francis (NIH/OD) [E]" [REDACTED] b6 >
Date: Saturday, March 27, 2021 at 12:55 PM
To: James Bradner [REDACTED] b6 >
Cc: "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED] b6 [REDACTED] b6 >
Subject: RE: [EXTERNAL] BGTC

Hey Jay,

Thanks for your note. That is wonderful news about Novartis and BGTC! I'd love to talk with you more about this. Would you have any time on Monday?

Best, Francis

From: Bradner, James [REDACTED] b6 >
Sent: Friday, March 26, 2021 1:20 PM
To: [REDACTED] b6 [REDACTED] b6
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 >; Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Subject: Re: [EXTERNAL] BGTC

thank you, [REDACTED] b6 for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated [REDACTED] (b) (4) this will surely be a good move [REDACTED] (b) (4) as such, the discovery and early [REDACTED] (b) (4) so i am getting up to speed on partnerships and collaborations.

could i put upon an NIH leader to meet and discuss the status of BGTC, [REDACTED] (b) (4) and i am hopeful they will remain as closely connected to this rising opportunity to work together as before.

best, jay

COLL0000013188

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[redacted] b6 | @jaybradner

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From: [redacted] b6 [redacted] b6
Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner [redacted] b6
Cc: David Wholley [redacted] b6, "Collins Francis [E]" [redacted] b6 >
Subject: Re: [EXTERNAL] BGTC

Jay

I and [redacted] (b) (4)

I ask David Wholley provide you w details

On [redacted] (b) (4)
[redacted]

Lessons learned [redacted] (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James [redacted] b6 > wrote:

thanks, [redacted] b6

[redacted] (b) (4)

best, jay





COLL0000013188

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 3/29/2021 5:18:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: [EXTERNAL] BGTC
Flag: Follow up

Joe and Steve are both available starting at 5:30.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
b6
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
   



From: Wholley, David (FNIH) [T] <b6>
Sent: Monday, March 29, 2021 1:17 PM
To: Collins, Francis (NIH/OD) [E] <b6>
Cc: Hoffmann, Steve (FNIH) [T] <b6> Menetski, Joseph (FNIH) [T] <b6> Melencio, Cheryl (FNIH) [T] <b6>
Subject: RE: [EXTERNAL] BGTC
Importance: High

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Cc: Hoffmann, Steve (FNIH) [T] <b6> >; Menetski, Joseph (FNIH) [T] <b6> Melencio, Cheryl (FNIH) [T] <b6> >
Subject: RE: [EXTERNAL] BGTC

Would 6 pm be better for you?

COLL0000013189

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To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Hoffmann, Steve (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] <[b6]>; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: [EXTERNAL] BGTC

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To: Wholley, David (FNIH) [T] <[b6]>
Subject: FW: [EXTERNAL] BGTC

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From: Bradner, James <[b6]>
Sent: Monday, March 29, 2021 12:16 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6], [b6], [b6]
Subject: Re: [EXTERNAL] BGTC

francis and david, thank you. i'd welcome any chance to connect. i am free today between 5p and 730p, and after 430p on tuesday and thursday. also, i have windows of flexibility tomorrow (tuesday) 230-330p and other odd times. i'd gladly connect to you both anytime. best wishes, jay

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President | Novartis Institutes for BioMedical Research
[b6] | @jaybradner

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From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Saturday, March 27, 2021 at 12:55 PM
To: James Bradner <[b6]>
Cc: "Wholley, David (FNIH) [T]" <[b6]>, [b6], [b6]
Subject: RE: [EXTERNAL] BGTC

Hey Jay,

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Best, Francis

From: Bradner, James <[REDACTED] b6 [REDACTED]>
Sent: Friday, March 26, 2021 1:20 PM
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President | Novartis Institutes for BioMedical Research
[REDACTED] b6 [REDACTED] | @jaybradner

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To: James Bradner [REDACTED] b6 [REDACTED]
Cc: David Wholley [REDACTED] b6 [REDACTED], "Collins Francis [E]" [REDACTED] b6 [REDACTED] >
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I and [REDACTED] (b) (4) [REDACTED]

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[REDACTED]

COLL0000013189

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Sent: 3/29/2021 5:19:02 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Flag: Follow up

Cheryl just let me know looks like we are all available at 5:30

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Sent: Monday, March 29, 2021 1:12 PM
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Cc: Hoffmann, Steve (FNIH) [T] <[REDACTED]> b6; Menetski, Joseph (FNIH) [T] <[REDACTED]> b6; Melencio, Cheryl (FNIH) [T] <[REDACTED]> b6
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Cc: Wholley, David (FNIH) [T] [REDACTED] b6 ; Collins, Francis (NIH/OD) [E] [REDACTED] b6
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COLL0000013192

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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Date: Friday, March 26, 2021 at 12:59 PM
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Cc: David Wholley b6, "Collins Francis [E]" b6 >
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Lessons learned (b) (4)

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President | Novartis Institutes for BioMedical Research

b6 | @jaybradner

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Subject: Re: [EXTERNAL] BGTC
Flag: Follow up

francis and david, thank you. i'd welcome any chance to connect. i am free today between 5p and 730p, and after 430p on tuesday and thursday. also, i have windows of flexibility tomorrow (tuesday) 230-330p and other odd times. i'd gladly connect to you both anytime. best wishes, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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From: "Collins, Francis (NIH/OD) [E]" < b6 >
Date: Saturday, March 27, 2021 at 12:55 PM
To: James Bradner < b6 >
Cc: "Wholley, David (FNIH) [T]" < b6 > b6 < b6 >
Subject: RE: [EXTERNAL] BGTC

Hey Jay,

Thanks for your note. That is wonderful news about Novartis and BGTC! I'd love to talk with you more about this. Would you have any time on Monday?

Best, Francis

From: Bradner, James < b6 >
Sent: Friday, March 26, 2021 1:20 PM
To: b6 < b6 >
Cc: Wholley, David (FNIH) [T] < b6 > Collins, Francis (NIH/OD) [E] < b6 >
Subject: Re: [EXTERNAL] BGTC

thank you, b6, for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated (b) (4). this will surely be a good move (b) (4) as such, the discovery and early (b) (4). so i am getting up to speed on partnerships and collaborations.

COLL0000013197

could i put upon an NIH leader to meet and discuss the status of BGTC, (b) (4) and i am hopeful they will remain as closely connected to this rising opportunity to work together as before.

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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From: b6 b6
Date: Friday, March 26, 2021 at 12:59 PM
To: James Bradner <b6>
Cc: David Wholley <b6> "Collins Francis [E]" <b6>
Subject: Re: [EXTERNAL] BGTC

Jay

I and (b) (4)

I ask David Wholley provide you w details

On (b) (4)

Lessons learned (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James <b6> wrote:

thanks, b6

(b) (4)

COLL0000013197

how best to get on board, review the status, meet the leaders, so as to take a near-term decision at NIBR?

best, jay

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

b6 | @jaybradner

From: [REDACTED]
Sent: 3/27/2021 4:56:05 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: [EXTERNAL] BGTC

Thanks

Sent from my iPhone

On Mar 27, 2021, at 12:55, Collins, Francis (NIH/OD) [E] <[REDACTED]> wrote:

Hey Jay,

Thanks for your note. That is wonderful news about Novartis and BGTC! I'd love to talk with you more about this. Would you have any time on Monday?

Best, Francis

From: Bradner, James <[REDACTED]>
Sent: Friday, March 26, 2021 1:20 PM
To: [REDACTED]
Cc: Wholley, David (FNIH) [T] <[REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED]>
Subject: Re: [EXTERNAL] BGTC

thank you, [REDACTED], for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated [REDACTED] (b) (4)
[REDACTED] (b) (4) this will surely be a good move [REDACTED] (b) (4)
[REDACTED] as such, the discovery and early [REDACTED] (b) (4)
[REDACTED] so i am getting up to speed on partnerships and collaborations.

could i put upon an NIH leader to meet and discuss the status of BGTC, [REDACTED] (b) (4)
[REDACTED]
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best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] | @jaybradner

<image002.jpg>

From: [REDACTED]
Date: Friday, March 26, 2021 at 12:59 PM

COLL0000013199

To: James Bradner <[REDACTED] b6 [REDACTED]>
Cc: David Wholley <[REDACTED] b6 [REDACTED]> "Collins Francis [E]" <[REDACTED] b6 [REDACTED]>
Subject: Re: [EXTERNAL] BGTC

Jay

I and [REDACTED] (b) (4) [REDACTED]

I ask David Wholley provide you w details

On [REDACTED] (b) (4) [REDACTED]
[REDACTED]

Lessons learned [REDACTED] (b) (4) [REDACTED]

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James <[REDACTED] b6 [REDACTED]> wrote:

thanks, [REDACTED] b6 [REDACTED]

[REDACTED] (b) (4) [REDACTED]

best, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] b6 [REDACTED] | @jaybradner

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 3/29/2021 5:05:15 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: [EXTERNAL] BGTC
Flag: Follow up

Yes, I can miss the last half hour of the USG Therapeutics call. I would like to have either Joe Menetski or Steve Hoffmann join the call, if possible, as they have been working this directly with the companies and can answer any detailed questions.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, March 29, 2021 1:02 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: RE: [EXTERNAL] BGTC

Oops, just had another call scheduled at 5 pm. Can you do 5:30?

From: Collins, Francis (NIH/OD) [E]
Sent: Monday, March 29, 2021 12:52 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: FW: [EXTERNAL] BGTC

Would you have time at 5 pm to talk with Jay?

From: Bradner, James [REDACTED] b6
Sent: Monday, March 29, 2021 12:16 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED] b6 [REDACTED] b6 >
Subject: Re: [EXTERNAL] BGTC

francis and david, thank you. i'd welcome any chance to connect. i am free today between 5p and 730p, and after 430p on tuesday and thursday. also, i have windows of flexibility tomorrow (tuesday) 230-330p and other odd times. i'd gladly connect to you both anytime. best wishes, jay

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] b6 | @jaybradner

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COLL0000013201

From: "Collins, Francis (NIH/OD) [E]" [REDACTED] b6

Date: Saturday, March 27, 2021 at 12:55 PM

To: James Bradner [REDACTED] b6

Cc: "Wholley, David (FNIH) [T]" [REDACTED] b6 [REDACTED] b [REDACTED] b6

Subject: RE: [EXTERNAL] BGTC

Hey Jay,

Thanks for your note. That is wonderful news about Novartis and BGTC! I'd love to talk with you more about this. Would you have any time on Monday?

Best, Francis

From: Bradner, James [REDACTED] b6

Sent: Friday, March 26, 2021 1:20 PM

To: [REDACTED] b6 <[REDACTED] b6 >

Cc: Wholley, David (FNIH) [T] [REDACTED] b6 >; Collins, Francis (NIH/OD) [E] [REDACTED] b6

Subject: Re: [EXTERNAL] BGTC

thank you, [REDACTED] b6 for the rapid correspondences here.

david and francis, as below, we have this month quietly and fully integrated [REDACTED] (b) (4). this will surely be a good move [REDACTED] (b) (4) as such, the discovery and early [REDACTED] (b) (4) so i am getting up to speed on partnerships and collaborations.

could i put upon an NIH leader to meet and discuss the status of BGTC, [REDACTED] (b) (4) and i am hopeful they will remain as closely connected to this rising opportunity to work together as before.

best, jay

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

[REDACTED] b6 | @jaybradner

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From: [REDACTED] b6 [REDACTED] b6

Date: Friday, March 26, 2021 at 12:59 PM

To: James Bradner <[REDACTED] b6 >

Cc: David Wholley [REDACTED] b6, "Collins Francis [E]" [REDACTED] b6 >

Subject: Re: [EXTERNAL] BGTC

Jay

COLL0000013201

I and (b) (4)

I ask David Wholley provide you w details

On (b) (4)

Lessons learned (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James b6 > wrote:

thanks, b6

(b) (4)

best, jay

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

b6 | @jaybradner

From: Bradner, James [REDACTED] b6
Sent: 3/29/2021 6:02:26 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Hoffmann, Steve (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=13ec7399e30a4385a232371d13af2479-hoffmanns]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: [EXTERNAL] BGTC

terrific, thank you francis.

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
[REDACTED] b6 | @jaybradner

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Pride@Novartis



From: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6>
Date: Monday, March 29, 2021 at 1:41 PM
To: James Bradner <[REDACTED] b6>
Cc: "Wholley, David (FNIH) [T]" <[REDACTED] b6> "Menetski, Joseph (FNIH) [T]" <[REDACTED] b6>
"Hoffmann, Steve (FNIH) [T]" <[REDACTED] b6> "Wood, Gretchen (NIH/OD) [E]" <[REDACTED] b6>
Subject: RE: [EXTERNAL] BGTC

Hey there Jay,

How about a call at 5:30 PM today? I'd like David Wholley, Joe Menetski, and Steve Hoffmann (all from FNIH) to join. I've looped in Gretchen Wood to ask her to set up a Zoom.

Francis

From: Bradner, James <[REDACTED] b6>
Sent: Monday, March 29, 2021 12:16 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Cc: Wholley, David (FNIH) [T] <[REDACTED] b6> [REDACTED] b6 [REDACTED] b6
Subject: Re: [EXTERNAL] BGTC

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COLL0000013202

Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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From: "Collins, Francis (NIH/OD) [E]" < b6 >
Date: Saturday, March 27, 2021 at 12:55 PM
To: James Bradner b6
Cc: "Wholley, David (FNIH) [T]" b6 > b6 b6
Subject: RE: [EXTERNAL] BGTC

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From: Bradner, James < b6 >
Sent: Friday, March 26, 2021 1:20 PM
To: b6 b6
Cc: Wholley, David (FNIH) [T] < b6 > Collins, Francis (NIH/OD) [E] < b6 >
Subject: Re: [EXTERNAL] BGTC

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Jay Bradner, M.D.
President | Novartis Institutes for BioMedical Research
b6 | @jaybradner

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COLL0000013202

From: b6 b6 >

Date: Friday, March 26, 2021 at 12:59 PM

To: James Bradner b6

Cc: David Wholley b6 >, "Collins Francis [E]" b6

Subject: Re: [EXTERNAL] BGTC

Jay

I and (b) (4)

I ask David Wholley provide you w details

On (b) (4)

Lessons learned (b) (4)

Sent from my iPhone

On Mar 26, 2021, at 12:30, Bradner, James <b6> wrote:

thanks, b6

(b) (4)

best, jay

Jay Bradner, M.D.

President | Novartis Institutes for BioMedical Research

b6 | @jaybradner

COLL0000013202

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 3/29/2021 6:42:41 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Re: [EXTERNAL] Funding request for Pfizer oral protease inhibitor
Flag: Follow up

The official sentiment from NIAID is that this would fit best with ACTIV-2x.

Cliff

From: "Wholley, David (FNIH) [T]" <[REDACTED]> b6
Date: Monday, March 29, 2021 at 1:14 PM
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> b6 Lawrence Tabak <[REDACTED]> b6
Cc: "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> b6 "Freire, Maria (FNIH) [T]" <[REDACTED]> b6 "Adam, Stacey (FNIH) [T]" <[REDACTED]> b6
Subject: FW: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Francis, and Larry,

Please see below and provide your guidance, as this is an NIH funding request.

(b) (5)

(b) (5)

Thanks, David

From: Bugin, Kevin <[REDACTED]> b6
Sent: Monday, March 29, 2021 12:38 PM
To: Kim, Peter (NIH/NIAID) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6 Johnson, Martin S. (NIH/NIAID) [E] <[REDACTED]> b6
Cc: Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Brooks, John (NIH/NIAID) [E] <[REDACTED]> b6 Erhardt, Bill (NIH/NIAID) [C] <[REDACTED]> b6 Read, Sarah (NIH/NIAID) [E] <[REDACTED]> b6
Subject: Re: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Did we explore the other options ? If so, and the answer was those other options will not work, then let's put it on the tracker and try to push it. We'll need to brief Dina and solicit her help in making the request. This is beyond the remit of Janet and I.

Kevin

From: Johnson, Martin S. (NIH/NIAID) [E] <[REDACTED]> b6
Sent: Monday, March 29, 2021 11:45:01 AM
To: Kim, Peter S (NIH) <[REDACTED]> b6 ; Bugin, Kevin <[REDACTED]> b6 ; Wholley, David N (NIH)

COLL0000013203

b6

Cc: Lane, Henry C (NIH) b6 > Brooks, John C (NIH) b6 Erhardt, Bill A (NIH)

b6 Read, Sarah W (NIH) b6

Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Kevin,

(b) (5)

Thanks

From: Kim, Peter (NIH/NIAID) [E] < b6 >

Sent: Thursday, March 18, 2021 11:33 AM

To: Bugin, Kevin (FDA/CDER) < b6 > Wholley, David (FNIH) [T] < b6 >

Cc: Lane, Cliff (NIH/NIAID) [E] b6 > Johnson, Martin S. (NIH/NIAID) [E] b6 ;

Brooks, John (NIH/NIAID) [E] b6 Erhardt, Bill (NIH/NIAID) [C] b6 Read,

Sarah (NIH/NIAID) [E] b6

Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi Kevin, David,

(b) (5)

me know. Also happy to undertake further discussion as needed.

Thanks,

Peter

COLL0000013203

From: Bugin, Kevin [b6]
Sent: Wednesday, March 17, 2021 7:25 PM
To: Wholley, David (FNIH) [T] <[b6]>
Cc: Kim, Peter (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Johnson, Martin S. (NIH/NIAID) [E] [b6]
Subject: RE: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

Hi David,

Looping in Martin Johnson.

So, my understanding is that [b6] (b) (5)

I guess two points for Dr. Collins:

1. [b6] (b) (5)
2. [b6]

Hope this is helpful!

Kevin

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, March 17, 2021 6:43 PM
To: Bugin, Kevin [b6]
Cc: Kim, Peter S (NIH) <[b6]> Lane, Henry C (NIH) [b6]
Subject: [EXTERNAL] Funding request for Pfizer oral protease inhibitor

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin—

Francis has agreed to help push this as a priority. He's asked who you've spoken with so far about this and who actually ultimately approves it (he's guessing David Kessler but wanted to make sure). Also, Peter, is there any kind of estimate of what NIAID would need to do this? Thanks, David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6 | fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



From: Rutter, Joni (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=157B2517DDB546A8A72844C35EADB062-JRUTTER]
Sent: 3/30/2021 7:07:35 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Hi Ashley,

I went back to review the slides that you sent and had a couple of comments. I am mainly reacting to the 7 themes (slide 8) because the deck was a bit overwhelming, but hopefully these will be helpful.

- Theme #1 is most helpful. A focus on governance is important so that it is clear how decisions get made and who is responsible for them.
- Themes 3-6 are focused on CTs – could consolidate these.
 - Theme 3 is a big lesson – there is a clear need for redundancy to be prepared for quickly staffing up sites to implement a good strategy for recruitment and have the resources and ability to engage all communities.
 - There is little return on cost—what's needed was time, effort, and resources. This mostly means that big, well-funded orgs are the only groups able to be responsive, but there somehow filling in the equity gaps would be a need.
 - Data collection and sharing plans need stronger guidance. It's an area where lead time is important, but not usually available. This could be a whole subsection, separating surveillance needs, trial needs, and research needs.
- The word "coordination" does not appear on the 7 themes, but that could be something to consider.
 - There were many times where sites/networks were working on 4-5 protocols and were chasing the same people for different protocols.
 - CARES funding preceding some of the planning efforts, and caused some initial confusion on early activities.

Best,
Joni

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, March 23, 2021 4:58 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6 Rutter, Joni (NIH/NCATS) [E] <[REDACTED]> b6 Anderson, James (NIH/OD) [E] <[REDACTED]> b6 Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]> b6
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Sharing the USG Tx Lessons Learned recommendations for review with the war room – happy to collect any feedback on these to share with Kevin and the group before the next follow up meeting early next week.

David – you may have seen these already given Mike and Stacey are involved with the ACTIV/NIH WG and PM teams respectively.

Thanks,
Ashley

From: Bugin, Kevin [b6] >
Sent: Monday, March 22, 2021 1:04 PM
To: Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Armstrong, Kimberly (OS/ASPR/BARDA) [b6]; Adam, Stacey (FNIH) [T] <[b6]>; Victoria Davey [b6]; Kilgore, Nicole R CIV USARMY (USA) [b6];
'[b6]' [b6] >
Cc: Teyhen, Deydre (HHS/IOS) <[b6]>; Erhardt, Bill (NIH/NIAID) [C] [b6]; Stone, Jessica <[b6]>; Tarnita, Roxana [b6]; King, Mason <[b6]>; Kristin Schneeman [b6]; 'Esther Krofah' [b6]; 'Dr Mark McClellan, M.D.' [b6]; 'Morgan Romine' <[b6]>; Santos, Michael (FNIH) [T] [b6]
Subject: [Pre-read] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Good afternoon,

Hope you are having a great start to your week and thank you again for helping steer the USG's Covid-19 Clinical Evaluation of Therapeutics Lessons Learned effort.

Over the past few weeks, together with numerous partners across the clinical research landscape who have worked together in Working Groups, we have compiled a broad array of lessons learned and have distilled these into select action-oriented recommendations that we are hoping to discuss with you tomorrow. We look forward to your review and guidance on which of these recommendations to pursue further as part of the next phase of the effort, which is focused on building detailed action plans to address the recommendations.

Ahead of the discussion, please find attached a pre-read of the materials we will be reviewing. We are aiming to spend the majority of the time tomorrow discussing the synthesized recommendations on slides 9-15. Additional information on recommendation development methodology and a more detailed set of recommendations from each of the Working Groups can be found on pages 19-23 and 25-41, respectively. If you are able to review these materials ahead of tomorrow, it will provide the opportunity for a much richer discussion and would be greatly appreciated.

I also want to take this opportunity to thank the leads of the Working Groups (copied) and all the members these groups who have invested a lot of time and effort into developing a great set of recommendations! The WG leads (copied) will be joining us tomorrow to help add the additional color commentary from their WG discussions and help answer any questions you may have.

Thank you and please don't hesitate to reach out with any questions. Looking forward to the discussion.

Best,
Kevin

-----Original Appointment-----

From: Woodcock, Janet <[REDACTED] b6 [REDACTED]>

Sent: Wednesday, February 10, 2021 1:53 PM

To: Woodcock, Janet; Ramakrishnan, Raahul; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Armstrong, Kimberly (OS); Adam, Stacey J (NIH); '[REDACTED] b6 [REDACTED]' Kilgore, Nicole R CIV USARMY (USA);

'[REDACTED] b6 [REDACTED]' Kristin Schneeman; 'Esther Krofah'; 'Dr Mark McClellan, M.D.'; 'Morgan Romine';

'[REDACTED] b6 [REDACTED]' Santos, Michael R (NIH)

Cc: Teyhen, Deydre (OS); Erhardt, Bill A (NIH)

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point

When: Tuesday, March 23, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Review progress of small working groups to kick-off and collate fact-base, approve prioritization from small working groups, and provide guidance on path to synthesis and public dissemination.

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Toll-free calling restrictions

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COLL0000013214

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/18/2021 2:20:52 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw
Flag: Follow up

Francis,
Stacey is not near her computer just now but texted me. FYI Stacey had already reached out to Adrian Hernandez at Janet's request—Janet just did not include that in her email to Josie. Also, we will try to get you the answer on fluvoxamine but as I said in war room our plan was to check back with Eric Lenze on his trial to see if he can move his trial forward before we try to place it in an ACTIV trial. Stacey did speak to Eric, and he told her recruitment is picking up. Finally strictly an editorial comment on my part but I have been part of trying to work with PCORnet since October on helping us accrue to the ACTIV studies and confidentially must say they do not strike me as the most responsive and agile organization out there. David

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Sunday, January 17, 2021 7:14 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Can you answer the question about placebo?

From: Woodcock, Janet <[REDACTED]> b6
Sent: Sunday, January 17, 2021 5:42 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

I don't know about fluvoxamine placebo. Would hope could randomize 1:1:1 but regimens may be different. Jw

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Date: January 17, 2021 at 4:26:55 PM EST
To: Woodcock, Janet <[REDACTED]> b6
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Hi Janet,

I just spoke with Josie Briggs about PCORnet possibly taking this on. Though she has some PTSD from the failed PCORnet project on HCQ, she can see the potential here, and will discuss it with Nakela. She says they may have some funds remaining from the HCQ outpatient study, since that was terminated early – but

probably that won't be enough if they are going to test both ivermectin and fluvoxamine. I have heard there is an ivermectin placebo ready to go – is that also available for fluvoxamine?

She gets it that there is some urgency here.

Francis

From: Woodcock, Janet <[REDACTED] b6>
Sent: Sunday, January 17, 2021 11:35 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Subject: FW: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

PCORNET would be the best bet I think. I may have trouble working on this starting WED, but is important to get done. Just don't know the vehicle, would need some sort of contract. But I think they would be the fastest. jw

From: Adrian Hernandez, M.D. <[REDACTED] b6>
Sent: Sunday, January 17, 2021 10:53 AM
To: Woodcock, Janet <[REDACTED] b6>
Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

Janet

Yes, could potentially take on depending on agent/requirements.

Let me know how best to learn more. Mobile is below if helpful.

Adrian

[REDACTED] b6

From: Janet Woodcock <[REDACTED] b6>
Date: Sunday, January 17, 2021 at 9:51 AM
To: "Adrian Hernandez, M.D." <[REDACTED] b6>
Subject: RE: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

I wanted to know if PRCORNET could potentially take on a large, pragmatic, potentially government-funded trial of relatively safe repurposed agents in outpatients with COVID-19. jw

From: Adrian Hernandez, M.D. <[REDACTED] b6>
Sent: Saturday, January 16, 2021 5:16 PM
To: [REDACTED] b6
Cc: Woodcock, Janet <[REDACTED] b6>
Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents?
jw

Hi

Just let me know what's needed

Adrian

b6

On Jan 16, 2021, at 5:06 PM, Robert Califf <[REDACTED]> wrote:

his email address is in the header--he'll respond.

flying back to NC to get vaccinated now. First flight in months.

rmc

On Sat, Jan 16, 2021 at 2:03 PM Woodcock, Janet <[REDACTED]> wrote:

Contact info? Tx jw

From: Robert Califf <[REDACTED]>

Sent: Saturday, January 16, 2021 4:57 PM

To: Woodcock, Janet <[REDACTED]> Adrian Hernandez, M.D.
<[REDACTED]>

Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

Adrian Hernandez is PI--

rmc

On Sat, Jan 16, 2021 at 1:55 PM Woodcock, Janet <[REDACTED]> wrote:

Yeah, but they match ACTIV 3. We should have more clinical data soon.

Need contact point for PCORNET not PCORI> jw

From: Robert Califf <[REDACTED]>

Sent: Saturday, January 16, 2021 12:12 PM

To: Woodcock, Janet <[REDACTED]>

Subject: Re: do you think PCORNET would be willing/able to mount a pragmatic outpatient trial of re-purposed agents? jw

yes; i think it would help it if you put public pressure on the org to deliver

will send more info

do you know when we'll have more readout from Lilly or Regeneron? Clinicians are skeptical and the Recovery conv plasma results aren't helping.

rmc

On Sat, Jan 16, 2021 at 8:48 AM Woodcock, Janet <[REDACTED]> wrote:

COLL0000013242

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/1/2021 10:19:54 PM
To: Rutter, Joni (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=157b2517ddb546a8a72844c35eadb062-jrutter]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021
Attachments: 210331 - Lessons Learned Initiative - Leadership Meeting_vShare.pptx

Thanks, Joni – apologies for the dense deck of slides (updated version attached isn't shorter!). I've added slide references in blue to your points below and will share the information provided with the USG Tx leads.

Thank you,
Ashley

From: Rutter, Joni (NIH/NCATS) [E] <[REDACTED]>
Sent: Tuesday, March 30, 2021 3:08 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> Wholley, David (FNIH) [T] <[REDACTED]> Lane, Cliff (NIH/NIAID) [E] <[REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED]> Anderson, James (NIH/OD) [E] <[REDACTED]> Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]> Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Hi Ashley,

I went back to review the slides that you sent and had a couple of comments. I am mainly reacting to the 7 themes (slide 8) because the deck was a bit overwhelming, but hopefully these will be helpful.

- Theme #1 is most helpful. A focus on governance is important so that it is clear how decisions get made and who is responsible for them. Slide 9 rec. 1.1
- Themes 3-6 are focused on CTs – could consolidate these.
 - Theme 3 is a big lesson – there is a clear need for redundancy to be prepared for quickly staffing up sites to implement a good strategy for recruitment and have the resources and ability to engage all communities. Slide 12 rec. 4.3 and slide 13 rec. 5.1 and 5.3. One key takeaway from the 3/31 meeting is to consider conducting a study to determine the most effective methods to increase trial participation from under-served communities.
 - There is little return on cost—what's needed was time, effort, and resources. This mostly means that big, well-funded orgs are the only groups able to be responsive, but there somehow filling in the equity gaps would be a need. Slide 14 rec. 5.4 but I will still flag for awareness.

- Data collection and sharing plans need stronger guidance. It's an area where lead time is important, but not usually available. This could be a whole subsection, separating surveillance needs, trial needs, and research needs. Slide 14 rec. 6.2
The word "coordination" does not appear on the 7 themes, but that could be something to consider. Primarily theme #1 slide 9 rec. 1.1, 1.2, 1.5
- There were many times where sites/networks were working on 4-5 protocols and were chasing the same people for different protocols. Noted – thank you.
- CARES funding preceding some of the planning efforts, and caused some initial confusion on early activities. Noted – thank you.

Best,
Joni

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, March 23, 2021 4:58 PM
To: Wholley, David (FNIH) [T] <[REDACTED]>; Lane, Cliff (NIH/NIAID) [E] <[REDACTED]>; Freire, Maria (FNIH) [T] <[REDACTED]>; Rutter, Joni (NIH/NCATS) [E] <[REDACTED]>; Anderson, James (NIH/OD) [E] <[REDACTED]>; Patterson, Amy (NIH/NHLBI) [E] <[REDACTED]>
Cc: Collins, Francis (NIH/OD) [E] <[REDACTED]>; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point - 03.23.2021

Sharing the USG Tx Lessons Learned recommendations for review with the war room – happy to collect any feedback on these to share with Kevin and the group before the next follow up meeting early next week.

David – you may have seen these already given Mike and Stacey are involved with the ACTIV/NIH WG and PM teams respectively.

Thanks,
Ashley

From: Bugin, Kevin <[REDACTED]>
Sent: Monday, March 22, 2021 1:04 PM
To: Woodcock, Janet (FDA/OC) <[REDACTED]>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[REDACTED]>; Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Armstrong, Kimberly (OS/ASPR/BARDA) <[REDACTED]>; Adam, Stacey (FNIH) [T] <[REDACTED]>; Victoria Davey <[REDACTED]>; Kilgore, Nicole R CIV USARMY (USA) <[REDACTED]>;
Cc: Teyhen, Deydre (HHS/IOS) <[REDACTED]>; Erhardt, Bill (NIH/NIAID) [C] <[REDACTED]>; Stone, Jessica <[REDACTED]>; Tarnita, Roxana <[REDACTED]>; King, Mason <[REDACTED]>; Kristin Schneeman <[REDACTED]>; 'Esther Krofah' <[REDACTED]>; 'Dr Mark McClellan, M.D.' <[REDACTED]>; 'Morgan Romine' <[REDACTED]>; Santos, Michael (FNIH) [T] <[REDACTED]>
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and guidance on which of these recommendations to pursue further as part of the next phase of the effort, which is focused on building detailed action plans to address the recommendations.

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Thank you and please don't hesitate to reach out with any questions. Looking forward to the discussion.

Best,
Kevin

-----Original Appointment-----

From: Woodcock, Janet [REDACTED] b6

Sent: Wednesday, February 10, 2021 1:53 PM

To: Woodcock, Janet; Ramakrishnan, Raahul; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Armstrong, Kimberly (OS); Adam, Stacey J (NIH); [REDACTED] b6; Kilgore, Nicole R CIV USARMY (USA);

[REDACTED] b6 Kristin Schneeman; 'Esther Krofah'; 'Dr Mark McClellan, M.D.'; 'Morgan Romine';

[REDACTED] b6 Santos, Michael R (NIH)

Cc: Teyhen, Deydre (OS); Erhardt, Bill A (NIH)

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Mid-point

When: Tuesday, March 23, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Review progress of small working groups to kick-off and collate fact-base, approve prioritization from small working groups, and provide guidance on path to synthesis and public dissemination.

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/14/2021 12:59:01 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: virus variants and Stoffels
Flag: Follow up

Hi Francis,

I am just answering this now because I have been traveling without access to email all afternoon and am just back online. (b) (5)

(b) (5)

(b) (5)

Sorry for the long note, but as you can see it is a complicated situation and there are a couple of things I thought you should know about.

David

From: Collins, Francis (NIH/OD) [E] < [REDACTED] b6 >
Sent: Wednesday, January 13, 2021 1:39 PM
To: Menetski, Joseph (FNIH) [T] < [REDACTED] b6 > Wholley, David (FNIH) [T] < [REDACTED] b6 >
Cc: Tabak, Lawrence (NIH/OD) [E] < [REDACTED] b6 >
Subject: FW: virus variants and Stoffels

Hi Joe and David,

See note below from Janet. [REDACTED] (b) (5)

Another note from Paul Stoffels – he will be on a plane tomorrow (first visit to the US since March) and will miss the LT. [REDACTED] (b) (5) Should we consider rescheduling?

FC

From: Woodcock, Janet [REDACTED] b6 >
Sent: Wednesday, January 13, 2021 1:16 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 >
Subject: virus variants

Francis I saw the proposal you made for ACTIV on this issue. Unfortunately, I'll not be able to be at all the exec comm meeting tomorrow.

As you probably know, OWS/therapeutics research group that includes NIAID folk are doing pseudovirus variant neut testing in CBER labs. Most of the MoAb sponsors have agreed to participate. The global circulating variants are being given priority.

We are also funding live virus testing for leading variants, that will start as soon as they get the virus.

CDER/FDA is interested in having a strategy in case variants start to predominate, both for AB development and I don't know about vaccines, haven't talked to Peter. They think a public meeting should be help on this at some point.

I'll try to come to as much of the exec comm as possible. Are you going to raise these issues here? jw

COLL0000013313

From: Brennan, Patti (NIH/NLM) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A15FB17E820C4A418B87B86DB1DFD6FF-BRENNANPF]
Sent: 1/19/2021 3:14:54 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: GISAID and data access limitations

Thanks for your personal attention to this matter.

Please know that NLM stands ready to help.

Patti

Patricia Flatley Brennan, RN, PhD
Director, National Library of Medicine
Investigator, National Institute of Nursing Research
National Institutes of Health
US Department of Health and Human Services

Telework: 830-5PM and by appointment

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> b6
Date: Monday, January 18, 2021 at 9:22 PM
To: "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" <[REDACTED]> b6
Cc: "Menetski, Joseph (FNIH) [T]" <[REDACTED]> b6 "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6
Patti Brennan <[REDACTED]> b6 Roger Glass <[REDACTED]> b6
"Kilmarx, Peter (NIH/FIC) [E]" <[REDACTED]> b6 "Eiss, Robert (NIH/FIC) [E]" <[REDACTED]> b6
Steve Sherry <[REDACTED]> b6
Subject: RE: GISAID and data access limitations

Hi Dan,

Thanks for this helpful context on GISAID. Given the link you mention with OGA and State, I'm looping in my Fogarty International Center colleagues.

(b) (5)

(b) (5)

I think we have a very strong humanitarian case.

Best, Francis

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> b6
Sent: Sunday, January 17, 2021 12:56 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6

COLL0000013314

Brennan, Patti (NIH/NLM) [E] < b6

Subject: RE: GISAID and data access limitations

Francis,

Also look forward to working with you on the big tasks ahead with variant viruses. Regarding GISAID, this is a complicated issue as you've pointed out. The database was stood up in 2008 for H5N1, but has been the primary repository for seasonal and novel influenza globally since that time. It is the recommended repository for influenza from WHO. The same was done for SARS-CoV-2. GISAID was stood up in an attempt to address significant problems that many nations were concerned about, including attribution of their work in subsequent publications and the use of their genetic sequence data in research and development. For this reason, the data use agreement reflects restrictions on the subsequent use of the data, and limits access to parties not agreeing to the data use agreement. Dave Wentworth serves on the Scientific Advisory Committee which works to improve accuracy and fidelity of the influenza sequences; however, that committee has not addressed the broader more fundamental issue you raise.

There are many aspects of GISAID that would benefit from improvement, both technical and, as you point out here, policy. To address changes to the existing GISAID DUA would require addressing the larger issue that many countries see as a protection of their work. Because of the multilateral participants in the issue, and with the strong connection to parts of WHO, CDC has been addressing GISAID policy issues through the HHS Office of Global Affairs and Department of State through Jonathon Margolis' office.

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Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office b6 Cell b6
b6 www.cdc.gov/flu

From: Collins, Francis (NIH/OD) [E] b6 >

Sent: Saturday, January 16, 2021 8:44 PM

To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) b6

Cc: Menetski, Joseph (FNIH) [T] < b6 Tabak, Lawrence (NIH/OD) [E] < b6

Brennan, Patti (NIH/NLM) [E] < b6

Subject: GISAID and data access limitations

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COLL0000013314

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Thanks for your help,

Francis

From: O'Connell, Dawn (HHS/IOS) [b6]
Sent: 4/9/2021 6:02:04 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: URGENT

Let me ping him. Sorry for missing Larry's email earlier.

From: Collins, Francis (NIH/OD) [E] < b6
Sent: Friday, April 9, 2021 1:50 PM
To: O'Connell, Dawn (HHS/IOS) < b6
Subject: URGENT

Any chance of some help here? Should I reach out to Sean directly? Truly sorry to bug you, but it's hard to watch the delay in launching this critical clinical trial that is ready to go now.

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Friday, April 9, 2021 10:44 AM
To: O'Connell, Dawn (HHS/IOS) b6
Cc: Tabak, Lawrence (NIH/OD) [E] b6; Rutter, Joni (NIH/NCATS) [E] b6 >; Wholley, David (FNIH) [T] < b6; Shapiro, Neil (NIH/OD) [E] b6 >
Subject: Seeking your help -- urgent

Hi Dawn,

With apologies for adding one more urgent item to your list for today, I am reaching out to ask for assistance in getting the funding memo for the ACTIV-6 clinical trial signed. ACTIV-6 is a protocol to test repurposed oral agents like ivermectin for outpatients just diagnosed with COVID-19. It has been considered for some time as a very high priority by myself, Janet Woodcock, and David Kessler. The protocol is all ready to go – in fact, we could have announced the launch today, but can't do so without assurance of the funds.

All that is needed is a signature from Sean McCluskie. I would be glad to contact him directly if you think that would be the best way to get this done, but I thought I would reach out to you first.

Please let me know if this is going to be possible. It really matters.

Thanks, Francis

From: Glass, Roger (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=03506BBBB1A2472790395288D4970BC0-GLASSR]
Sent: 1/19/2021 11:59:52 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=504f61b222f148348e5f1a8c1fc6aa07-DBJ0]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Kilmarx, Peter (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ecf449bd7044ba9fd585c8da4d47b4-kilmarxph]; Spiro, David (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfe0d2b827c94f73ad0df4d1ca369322-spirodj]; Viboud, Cecile (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b9f810e155840289c866da0aa36c0aa-viboudc]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Officer, Jackie (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f79d039e79844c0932985349a2921d6-officerjm]
Subject: Fwd: GISAID and data access limitations
Flag: Follow up

Good morning Dan

We have a flu /COVID modeling group at Fogarty who are quite involved with GISAID and feel your pain. I will ask Jackie Officer in my office to set up a time to speak with the group today.

Roger

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Sent from my iPhone

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Date: January 18, 2021 at 9:33:08 PM EST
To: "Spiro, David (NIH/FIC) [E]" <[REDACTED] b6> "Viboud, Cecile (NIH/FIC) [E]" <[REDACTED] b6>
Cc: "Glass, Roger (NIH/FIC) [E]" <[REDACTED] b6> "Eiss, Robert (NIH/FIC) [E]" <[REDACTED] b6>
Subject: Re: GISAID and data access limitations

David and Cecile - FYI for discussion tomorrow.

(Dan and I were in the same EIS class at CDC.)

Peter Kilmarx
Fogarty International Center

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COLL0000013326

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COLL0000013326

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Sent: 1/19/2021 12:20:55 PM
To: Glass, Roger (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbbb1a2472790395288d4970bc0-glassr]
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Subject: RE: GISAID and data access limitations

Thanks. Nice to hear from you all. Will reach out to Larry and OGA to help engage.

Thanks

Dan.

From: Glass, Roger (NIH/FIC) [E] < b6 >
Sent: Tuesday, January 19, 2021 7:00 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < b6 >
Cc: Collins, Francis (NIH/OD) [E] < b6 > Kilmarx, Peter (NIH/FIC) [E] < b6 > Spiro, David (NIH/FIC) [E] < b6 > Viboud, Cecile (NIH/FIC) [E] < b6 > Brennan, Patti (NIH/NLM) [E] < b6 > Officer, Jackie (NIH/FIC) [E] < b6 >
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COLL0000013335

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Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6 ; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Brennan, Patti (NIH/NLM) [E] [REDACTED] b6
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Subject: RE: GISAID and data access limitations
Flag: Follow up

Thanks. Adding Larry Kerr to help guide us through the complicated multilateral space, also to let us know if this global sequencing issues are on the agenda or being discussed at the WHO Executive Board this week.

Thanks

Dan.

Daniel B. Jernigan, MD MPH
Director, Influenza Division
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1600 Clifton Rd NE, Atlanta, GA 30329
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[b6] www.cdc.gov/flu

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Monday, January 18, 2021 9:22 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[b6]>
Cc: Menetski, Joseph (FNIH) [T] <[b6]> Tabak, Lawrence (NIH/OD) [E] <[b6]>
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Thanks for your help,

Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/12/2021 10:58:40 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14
Flag: Follow up

Sounds good to me – Francis, are you OK with giving Kevin and Janet the full 30 mins? I will send them the dial-in information once I have the green light.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Monday, April 12, 2021 6:50 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

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From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, April 12, 2021 5:51 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Wholley, David (FNIH) [T] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 Freire, Maria (FNIH) [T] <[REDACTED]> b6
Subject: Re: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

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Hopefully 15 mins will be enough time — seem OK?

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This looks like a good list. And we can be generous and allow him 15 minutes.

FC

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To: Wholley, David (FNIH) [T] b6 ; Collins, Francis (NIH/OD) [E] < b6
Cc: Tabak, Lawrence (NIH/OD) [E] b6 ; Freire, Maria (FNIH) [T]
< b6
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Agree – please see addition below. Does this work?

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Sent: Monday, April 12, 2021 11:51 AM
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< b6
Cc: Tabak, Lawrence (NIH/OD) [E] b6 ; Freire, Maria (FNIH) [T]
< b6
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Cc: Tabak, Lawrence (NIH/OD) [E] < b6 Wholley, David (FNIH) [T]
b6
Subject: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

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I standby for any edits before sending to Kevin and please let me know if I need to amend the time.

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COLL0000013359

To provide more context and clarity for the discussion, the war room has seen the large slide sets for the USG Tx Lessons Learned, USG Tx Strategy, and possibly other slides that have been shared through some of the other USG Tx workstreams and I agree the group would benefit from understanding the USG Tx organizational structure with all of the various components of the workstreams/activities in an effort to fully capture the USG Tx activities and overarching goals. In addition, below are a few questions that may arise and help bring clarity.

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Thank you,
Ashley

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Sent: Monday, April 12, 2021 10:57 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: War Room this week

Hi Ashley,

I hope you had a nice weekend!

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Kevin

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 1/19/2021 2:41:50 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=504f61b222f148348e5f1a8c1fc6aa07-DBJ0]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Kerr, Lawrence (HHS/OS/OGA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d0ddab07bc44eedae01c21b160c30c1-Lawrence.Ke]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Glass, Roger (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbb1a2472790395288d4970bc0-glassr]; Kilmarx, Peter (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ecf449bd7044ba9fd585c8da4d47b4-kilmarxph]; Eiss, Robert (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=707887ee7ba548e1a0ae55f683ce2017-eissr]; Sherry, Steve (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3339a3f0862046b78f97a029c4753bf3-sherry]
Subject: Re: GISAID and data access limitations
Flag: Follow up
+ Carrie

From: "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" <[REDACTED]>
Date: Tuesday, January 19, 2021 at 7:33 AM
To: Francis Collins <[REDACTED]> Lawrence Kerr <[REDACTED]>
Cc: "Menetski, Joseph (FNIH) [T]" <[REDACTED]> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> "Brennan, Patti (NIH/NLM) [E]" <[REDACTED]> "Glass, Roger (NIH/FIC) [E]" <[REDACTED]> "Kilmarx, Peter (NIH/FIC) [E]" <[REDACTED]> "Eiss, Robert (NIH/FIC) [E]" <[REDACTED]> "Sherry, Steve (NIH/NLM/NCBI) [E]" <[REDACTED]>
Subject: RE: GISAID and data access limitations

Thanks. Adding Larry Kerr to help guide us through the complicated multilateral space, also to let us know if this global sequencing issues are on the agenda or being discussed at the WHO Executive Board this week.
Thanks
Dan.

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office [REDACTED] Cell [REDACTED]
[REDACTED], www.cdc.gov/flu

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, January 18, 2021 9:22 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> b6
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6
Brennan, Patti (NIH/NLM) [E] <[REDACTED]> b6 Glass, Roger (NIH/FIC) [E] <[REDACTED]> b6 Kilmarx, Peter (NIH/FIC) [E] <[REDACTED]> b6 Eiss, Robert (NIH/FIC) [E] <[REDACTED]> b6 Sherry, Steve (NIH/NLM/NCBI) [E] <[REDACTED]> b6
Subject: RE: GISAID and data access limitations

Hi Dan,

Thanks for this helpful context on GISAID. Given the link you mention with OGA and State, I'm looping in my Fogarty International Center colleagues.

(b) (5)

(b) (5)

I think

we have a very strong humanitarian case.

Best, Francis

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> b6
Sent: Sunday, January 17, 2021 12:56 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> b6 >; Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6
Brennan, Patti (NIH/NLM) [E] <[REDACTED]> b6 >
Subject: RE: GISAID and data access limitations

Francis,

Also look forward to working with you on the big tasks ahead with variant viruses. Regarding GISAID, this is a complicated issue as you've pointed out. The database was stood up in 2008 for H5N1, but has been the primary repository for seasonal and novel influenza globally since that time. It is the recommended repository for influenza from WHO. The same was done for SARS-CoV-2. GISAID was stood up in an attempt to address significant problems that many nations were concerned about, including attribution of their work in subsequent publications and the use of their genetic sequence data in research and development. For this reason, the data use agreement reflects restrictions on the subsequent use of the data, and limits access to parties not agreeing to the data use agreement. Dave Wentworth serves on the Scientific Advisory Committee which works to improve accuracy and fidelity of the influenza sequences; however, that committee has not addressed the broader more fundamental issue you raise.

There are many aspects of GISAID that would benefit from improvement, both technical and, as you point out here, policy. To address changes to the existing GISAID DUA would require addressing the larger issue that many countries see as a protection of their work. Because of the multilateral participants in the issue, and with the strong connection to parts of WHO, CDC has been addressing GISAID policy issues through the HHS Office of Global Affairs and Department of State through Jonathon Margolis' office.

I agree with you that we really need a better global sequencing solution, but given the timing of transition and the thaw in relationships with WHO, I would recommend putting the GISAID access policy issues into the broader ongoing discussion of USG's near-term strategic discussions with WHO and other global partners. To change the data use policy will require other nations to communicate the same message and solutions. Happy to have a further discussion if that would be useful.

Thanks
Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office [b6] Cell [b6]
[b6] www.cdc.gov/flu

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Saturday, January 16, 2021 8:44 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[b6]>
Cc: Menetski, Joseph (FNIH) [T] <[b6]> Tabak, Lawrence (NIH/OD) [E] <[b6]>
Brennan, Patti (NIH/NLM) [E] <[b6]>
Subject: GISAID and data access limitations

Dear Dan,

Thanks very much for the opportunity to work with you and CDC on the increasingly serious issue of mutations in SARS-CoV-2 that might affect the efficacy of vaccines and monoclonal antibodies.

I wanted to ask your advice about the GISAID database. I know this was originally developed during the H5N1 influenza outbreak. GISAID then stepped forward in 2020 to make its capabilities available in the context of the threats from SARS-CoV-2. That was a good thing, but unfortunately I understand that GISAID strictly limits access to data. This will block some of the plans for the new NCBI database the ACTIV project is proposing, and seems like the wrong model in the midst of a global pandemic.

I hope the GISAID leadership might be willing to reconsider this policy. Is this something that you have already approached? I would think the CDC SPHERES project would be particularly interested in encouraging open access across the world for this kind of data, especially with the rapid emergence of new SARS-CoV-2 variants that may have major significance. From the web, I see that David Wentworth of CDC is on the GISAID Scientific Advisory Committee, could he help make this case?

On behalf of NIH (including NCBI/NLM and NIAID) I am flagging this as an important issue. I would like to work with CDC in seeking a more open approach by GISAID. I would bet that Rochelle Walensky would also support this. Can I get your advice on how this might be best approached?

Thanks for your help,

Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 4/13/2021 12:45:16 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14
Flag: Follow up

Ok - thanks

From: Francis Collins <[REDACTED] b6 [REDACTED]>
Date: Monday, April 12, 2021 at 8:44 PM
To: "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Subject: RE: USG Tx Lesson Learned | War Room Discussion on Wednesday 4/14

Yes, if Janet is joining we should certainly extend that courtesy.

FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Monday, April 12, 2021 6:59 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 [REDACTED]> Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>
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Cc: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 >; Freire, Maria (FNIH) [T] [REDACTED] b6
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Sent: Monday, April 12, 2021 11:51 AM
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Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6>; Freire, Maria (FNIH) [T] [REDACTED] b6
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From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 1/19/2021 3:09:23 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: GISAID and data access limitations

Hey Francis,

Just FYI, Larry Kerr sent me a separate note about this, because OGA has apparently been doing a ton of work to solve this problem and there are already a lot of chefs in the kitchen. He is THRILLED you are taking the lead, he just wants to make sure you have all of the background on previous conversations. I offered to hop on the phone with him (probably with Rob Eiss) and get that download so I can share it with you. Cheers, Carrie

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]>
Sent: Tuesday, January 19, 2021 9:42 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <[REDACTED]> Collins, Francis (NIH/OD) [E] <[REDACTED]>
Kerr, Lawrence (HHS/OS/OGA) <[REDACTED]> Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]>
Cc: Menetski, Joseph (FNIH) [T] <[REDACTED]> Brennan, Patti (NIH/NLM) [E] <[REDACTED]> Glass, Roger (NIH/FIC) [E] <[REDACTED]> Kilmarx, Peter (NIH/FIC) [E] <[REDACTED]> Eiss, Robert (NIH/FIC) [E] <[REDACTED]> Sherry, Steve (NIH/NLM/NCBI) [E] <[REDACTED]>
Subject: Re: GISAID and data access limitations

+ Carrie

From: "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" <[REDACTED]>
Date: Tuesday, January 19, 2021 at 7:33 AM
To: Francis Collins <[REDACTED]>, Lawrence Kerr <[REDACTED]>
Cc: "Menetski, Joseph (FNIH) [T]" <[REDACTED]> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]>, "Brennan, Patti (NIH/NLM) [E]" <[REDACTED]>, "Glass, Roger (NIH/FIC) [E]" <[REDACTED]>, "Kilmarx, Peter (NIH/FIC) [E]" <[REDACTED]>, "Eiss, Robert (NIH/FIC) [E]" <[REDACTED]>, "Sherry, Steve (NIH/NLM/NCBI) [E]" <[REDACTED]>
Subject: RE: GISAID and data access limitations

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Thanks
Dan.

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office [REDACTED] Cell [REDACTED]
[REDACTED] www.cdc.gov/flu

COLL0000013387

From: Collins, Francis (NIH/OD) [E] b6
Sent: Monday, January 18, 2021 9:22 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < b6
Cc: Menetski, Joseph (FNIH) [T] b6 Tabak, Lawrence (NIH/OD) [E] b6
Brennan, Patti (NIH/NLM) [E] b6 >; Glass, Roger (NIH/FIC) [E] b6 ; Kilmarx, Peter
(NIH/FIC) [E] b6 >; Eiss, Robert (NIH/FIC) [E] b6 >; Sherry, Steve (NIH/NLM/NCBI)
[E] b6 >
Subject: RE: GISAID and data access limitations

Hi Dan,

Thanks for this helpful context on GISAID. Given the link you mention with OGA and State, I'm looping in my Fogarty International Center colleagues.

(b) (5)

(b) (5)

I think

we have a very strong humanitarian case.

Best, Francis

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < b6
Sent: Sunday, January 17, 2021 12:56 PM
To: Collins, Francis (NIH/OD) [E] < b6
Cc: Menetski, Joseph (FNIH) [T] b6 >; Tabak, Lawrence (NIH/OD) [E] < b6
Brennan, Patti (NIH/NLM) [E] b6 >
Subject: RE: GISAID and data access limitations

Francis,

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I agree with you that we really need a better global sequencing solution, but given the timing of transition and the thaw in relationships with WHO, I would recommend putting the GISAID access policy issues into the broader ongoing discussion of USG's near-term strategic discussions with WHO and other global partners. To change the data use policy

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Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6>; Brennan, Patti (NIH/NLM) [E] [REDACTED] b6
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On behalf of NIH (including NCBI/NLM and NIAID) I am flagging this as an important issue. I would like to work with CDC in seeking a more open approach by GISAID. I would bet that Rochelle Walensky would also support this. Can I get your advice on how this might be best approached?

Thanks for your help,

Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/14/2021 1:26:06 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: wanted to be sure you saw this

Flag: Follow up

Hi Francis,

It is the first I have heard (b) (5)

(b) (5)

I can't guarantee they will all show up, and it is ultimately up to you, of course, but that is my 2 cents. Please let me know what you'd like to do.

David

From: Collins, Francis (NIH/OD) [E] < > b6

Sent: Wednesday, January 13, 2021 5:21 PM

To: Wholley, David (FNIH) [T] < > b6

Subject: wanted to be sure you saw this

With Stoffels not able to join the LT tomorrow, should we consider postponing?

From: Collins, Francis (NIH/OD) [E]

Sent: Wednesday, January 13, 2021 1:39 PM

To: Menetski, Joseph (FNIH) [T] < > b6 Wholley, David (FNIH) [T] < > b6

Cc: Tabak, Lawrence (NIH/OD) [E] < > b6

Subject: FW: virus variants and Stoffels

Hi Joe and David,

See note below from Janet. (b) (5)

Another note from Paul Stoffels – (b) (6)

(b) (5). Should we consider rescheduling?

FC

From: Woodcock, Janet < > b6

Sent: Wednesday, January 13, 2021 1:16 PM

To: Collins, Francis (NIH/OD) [E] < > b6

Subject: virus variants

COLL0000013392

Francis I saw the proposal you made for ACTIV on this issue. Unfortunately, I'll not be able to be at all the exec comm meeting tomorrow.

As you probably know, OWS/therapeutics research group that includes NIAID folk are doing pseudovirus variant neut testing in CBER labs. Most of the MoAb sponsors have agreed to participate. The global circulating variants are being given priority.

We are also funding live virus testing for leading variants, that will start as soon as they get the virus.

CDER/FDA is interested in a having a strategy in case variants start to predominate, both for AB development and I don't know about vaccines, haven't talked to Peter. They think a public meeting should be help on this at some point.

I'll try to come to as much of the exec comm as possible. Are you going to raise these issues here? jw

From: Eiss, Robert (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=707887EE7BA548E1A0AE55F683CE2017-EISSR]
Sent: 1/19/2021 8:00:12 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=504f61b222f148348e5f1a8c1fc6aa07-DBJ0]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiip]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Brennan, Patti (NIH/NLM) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a15fb17e820c4a418b87b86db1dfd6ff-brennanpf]; Glass, Roger (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03506bbb1a2472790395288d4970bc0-glassr]; Kilmarx, Peter (NIH/FIC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4ecf449bd7044ba9fd585c8da4d47b4-kilmarxph]; Sherry, Steve (NIH/NLM/NCBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3339a3f0862046b78f97a029c4753bf3-sherry]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: GISAID and data access limitations
Attachments: WHO Exec Board TPs.docx

Hi Francis,

This topic might emerge during the virtual session of the WHO Executive Board on Thursday, during discussion on “The public health implications of implementation of the Nagoya Protocol.” Nagoya as you likely know is the multilateral treaty that established a legal framework for utilizing genetic resources. Attached are draft US talking points on SARS-CoV-2 data and sample sharing, assembled by HHS/OGA, which include the following broad statement:

Unduly restricting or slowing down access to genetic sequence data (GSD) or other types of information could undermine the ability to rapidly respond to novel or recurring outbreaks of pathogens with pandemic or epidemic potential, placing human lives at risk

WHO has promoted the depositing of sequences in GISAID as opposed to other open access databases, which has been problematic.

GISAID is exploring expansion beyond influenza and SARS-CoV-2 to other respiratory pathogens, and perhaps other pathogen types.

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COLL0000013414

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Sent: 4/20/2021 1:57:37 AM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Subject: Re: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans
Flag: Follow up

Kevin,
Francis is off-line but I believe he would greatly appreciate a check in with you tomorrow at 8am if that is possible. Please let me know and I will set up a zoom call before turning in this evening.
Thanks for considering.
Best wishes,
Larry

From: "Bugin, Kevin" <[REDACTED]>
Date: Monday, April 19, 2021 at 9:30 PM
To: Francis Collins <[REDACTED]>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> "Wholley, David (FNIH) [T]" <[REDACTED]> "Freire, Maria (FNIH) [T]" <[REDACTED]> "Parker, Ashley (NIH/OD) [E]" <[REDACTED]>
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Kevin

COLL0000013426

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, April 19, 2021 9:02 PM
To: Bugin, Kevin <[REDACTED]> b6
Cc: Tabak, Lawrence A (NIH) <[REDACTED]> b6 Wholley, David N (NIH) <[REDACTED]> b6 Freire, Maria C (NIH) <[REDACTED]> b6 Parker, Ashley S (NIH) <[REDACTED]> b6
Subject: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

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Could you be available for a 45-minute call or Zoom with me and the folks in the cc line tomorrow at 8 AM?

Thanks, Francis

From: Bugin, Kevin [REDACTED] b6
Sent: 4/20/2021 2:00:20 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
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Subject: Re: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans
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Sure. I may or may not be able to be on video by then. I have a dental appointment at 7 am. Should be back online by then, but will at least be available by phone.

Kevin

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, April 19, 2021 9:57:37 PM
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Cc: Wholley, David N (NIH) <[REDACTED] b6> Freire, Maria C (NIH) <[REDACTED] b6> Parker, Ashley S (NIH) <[REDACTED] b6>
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Flag: Follow up

Many thanks
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Cc: "Wholley, David (FNIH) [T]" <[REDACTED]> b6 "Freire, Maria (FNIH) [T]" <[REDACTED]> b6 "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> b6
Subject: Re: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

Sure. I may or may not be able to be on video by then. I have a dental appointment at 7 am. Should be back online by then, but will at least be available by phone.

Kevin

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, April 19, 2021 9:57:37 PM
To: Bugin, Kevin <[REDACTED]> b6 Collins, Francis S (NIH) <[REDACTED]> b6
Cc: Wholley, David N (NIH) <[REDACTED]> b6 Freire, Maria C (NIH) <[REDACTED]> b6 Parker, Ashley S (NIH) <[REDACTED]> b6
Subject: Re: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Kevin,
Francis is off-line but I believe he would greatly appreciate a check in with you tomorrow at 8am if that is possible. Please let me know and I will set up a zoom call before turning in this evening.
Thanks for considering.
Best wishes,
Larry

From: "Bugin, Kevin" <[REDACTED]> b6
Date: Monday, April 19, 2021 at 9:30 PM

COLL0000013432

To: Francis Collins <[REDACTED] b6>
Cc: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6> "Wholley, David (FNIH) [T]"
<[REDACTED] b6> "Freire, Maria (FNIH) [T]" <[REDACTED] b6> "Parker, Ashley (NIH/OD) [E]"
<[REDACTED] b6>
Subject: RE: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

Hi Francis,

This is what I know about the presentation David Kessler is giving to the WH next week:

"David will be making a presentation at the White House next week about plans for an anti-viral program. While he is there, he would like to provide an update on the ACTIV program."

Stacey Adam is helping pull together these slides, with a midday Wed deadline, which would focus on providing information about each ACTIV trial, such as agents being tested, their status, etc. There are no plans, that I am aware of, to share anything from the lessons learned work. It's no where near ready for that!! And, David would not have the slides you sent over and we have not provided him with any update with that level of detail yet.

Hope this lowers blood pressures. And, also happy to provide an additional update on the lessons learned work. I could probably make 8 am work tomorrow. But I think waiting until next week would be better as we have our last full working group meeting this Thursday and the recommendations/proposed action plans will be in a better place thereafter. Let me know.

Thanks,

Kevin

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, April 19, 2021 9:02 PM
To: Bugin, Kevin <[REDACTED] b6>
Cc: Tabak, Lawrence A (NIH) <[REDACTED] b6> Wholley, David N (NIH) <[REDACTED] b6> Freire, Maria C (NIH) <[REDACTED] b6> Parker, Ashley S (NIH) <[REDACTED] b6>
Subject: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin,

I heard indirectly through David Wholley that there is a set of ppts that need to be reviewed and approved by Wednesday, and that might be used for some sort of presentation to the White House by David Kessler. I assume the attached ppt file is what is being discussed.

Kevin, I am getting increasingly concerned about the path being travelled by these plans. While there have been some NIH reps taking part in your process, and no doubt they could have done a better job of informing the rest of us, I am mostly in the dark about where this is going – as are Larry Tabak, David Wholley, and Maria Freire. We were all appreciative of your presentation to the War Room last Wednesday, but the time was too short to clarify a lot of the areas of confusion.

Could you be available for a 45-minute call or Zoom with me and the folks in the cc line tomorrow at 8 AM?

Thanks, Francis

COLL0000013432

From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 1/19/2021 9:44:41 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: GISAID and data access limitations
Flag: Follow up

Will do. We are talking Thursday afternoon and will send you a summary immediately after.

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]> b6
Date: Tue, Jan 19, 2021, 4:34 PM
To: "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED]> b6
Subject: RE: GISAID and data access limitations

It would be GREAT if you would get that download! I need to follow up with Trevor and Jeremy but I will wait for your input.

FC

From: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, January 19, 2021 10:09 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: FW: GISAID and data access limitations

Hey Francis,

Just FYI, Larry Kerr sent me a separate note about this, because OGA has apparently been doing a ton of work to solve this problem and there are already a lot of chefs in the kitchen. He is THRILLED you are taking the lead, he just wants to make sure you have all of the background on previous conversations. I offered to hop on the phone with him (probably with Rob Eiss) and get that download so I can share it with you. Cheers, Carrie

From: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, January 19, 2021 9:42 AM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [REDACTED] b6 ; Collins, Francis (NIH/OD) [E] [REDACTED] b6
Kerr, Lawrence (HHS/OS/OGA) [REDACTED] b6 ; Wolinetz, Carrie (NIH/OD) [E] [REDACTED] b6
Cc: Menetski, Joseph (FNIH) [T] [REDACTED] b6 ; Brennan, Patti (NIH/NLM) [E] <[REDACTED]> b6 ; Glass, Roger (NIH/FIC) [E] <[REDACTED]> b6 ; Kilmarx, Peter (NIH/FIC) [E] <[REDACTED]> b6 ; Eiss, Robert (NIH/FIC) [E] [REDACTED] b6 ; Sherry, Steve (NIH/NLM/NCBI) [E] [REDACTED] b6
Subject: Re: GISAID and data access limitations

+ Carrie

From: "Jernigan, Daniel B. (CDC/DDID/NCIRD/ID)" [REDACTED] b6
Date: Tuesday, January 19, 2021 at 7:33 AM
To: Francis Collins [REDACTED] b6 >, Lawrence Kerr [REDACTED] b6
Cc: "Menetski, Joseph (FNIH) [T]" [REDACTED] b6, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6, "Brennan, Patti (NIH/NLM) [E]" [REDACTED] b6, "Glass, Roger (NIH/FIC)" [REDACTED] b6

[E]" < [b6] "Kilmarx, Peter (NIH/FIC) [E]" < [b6] "Eiss, Robert (NIH/FIC)
[E]" < [b6] "Sherry, Steve (NIH/NLM/NCBI) [E]" [b6]

Subject: RE: GISAID and data access limitations

Thanks. Adding Larry Kerr to help guide us through the complicated multilateral space, also to let us know if this global sequencing issues are on the agenda or being discussed at the WHO Executive Board this week.

Thanks

Dan.

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office [b6] Cell [b6]
[b6] www.cdc.gov/flu

From: Collins, Francis (NIH/OD) [E] < [b6] >
Sent: Monday, January 18, 2021 9:22 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) [b6]
Cc: Menetski, Joseph (FNIH) [T] < [b6] >; Tabak, Lawrence (NIH/OD) [E] < [b6] >; Brennan, Patti (NIH/NLM) [E] [b6]; Glass, Roger (NIH/FIC) [E] [b6]; Kilmarx, Peter (NIH/FIC) [E] [b6]; Eiss, Robert (NIH/FIC) [E] [b6]; Sherry, Steve (NIH/NLM/NCBI) [E] [b6]
Subject: RE: GISAID and data access limitations

Hi Dan,

Thanks for this helpful context on GISAID. Given the link you mention with OGA and State, I'm looping in my Fogarty International Center colleagues.

(b) (5)

(b) (5)

I think we have a very strong humanitarian case.

Best, Francis

From: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < [b6] >
Sent: Sunday, January 17, 2021 12:56 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Brennan, Patti (NIH/NLM) [E] < [b6] >
Subject: RE: GISAID and data access limitations

Francis,

Also look forward to working with you on the big tasks ahead with variant viruses. Regarding GISAID, this is a complicated issue as you've pointed out. The database was stood up in 2008 for H5N1, but has been the primary

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repository for seasonal and novel influenza globally since that time. It is the recommended repository for influenza from WHO. The same was done for SARS-CoV-2. GISAID was stood up in an attempt to address significant problems that many nations were concerned about, including attribution of their work in subsequent publications and the use of their genetic sequence data in research and development. For this reason, the data use agreement reflects restrictions on the subsequent use of the data, and limits access to parties not agreeing to the data use agreement. Dave Wentworth serves on the Scientific Advisory Committee which works to improve accuracy and fidelity of the influenza sequences; however, that committee has not addressed the broader more fundamental issue you raise.

There are many aspects of GISAID that would benefit from improvement, both technical and, as you point out here, policy. To address changes to the existing GISAID DUA would require addressing the larger issue that many countries see as a protection of their work. Because of the multilateral participants in the issue, and with the strong connection to parts of WHO, CDC has been addressing GISAID policy issues through the HHS Office of Global Affairs and Department of State through Jonathon Margolis' office.

I agree with you that we really need a better global sequencing solution, but given the timing of transition and the thaw in relationships with WHO, I would recommend putting the GISAID access policy issues into the broader ongoing discussion of USG's near-term strategic discussions with WHO and other global partners. To change the data use policy will require other nations to communicate the same message and solutions. Happy to have a further discussion if that would be useful.

Thanks

Dan

Daniel B. Jernigan, MD MPH
Director, Influenza Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention
1600 Clifton Rd NE, Atlanta, GA 30329
Office b6 Cell b6
b6 www.cdc.gov/fiu

From: Collins, Francis (NIH/OD) [E] < b6 >
Sent: Saturday, January 16, 2021 8:44 PM
To: Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) < b6 >
Cc: Menetski, Joseph (FNIH) [T] b6 Tabak, Lawrence (NIH/OD) [E] b6 ;
Brennan, Patti (NIH/NLM) [E] < b6 >
Subject: GISAID and data access limitations

Dear Dan,

Thanks very much for the opportunity to work with you and CDC on the increasingly serious issue of mutations in SARS-CoV-2 that might affect the efficacy of vaccines and monoclonal antibodies.

I wanted to ask your advice about the GISAID database. I know this was originally developed during the H5N1 influenza outbreak. GISAID then stepped forward in 2020 to make its capabilities available in the context of the threats from SARS-CoV-2. That was a good thing, but unfortunately I understand that GISAID strictly limits access to data. This will block some of the plans for the new NCBI database the ACTIV project is proposing, and seems like the wrong model in the midst of a global pandemic.

I hope the GISAID leadership might be willing to reconsider this policy. Is this something that you have already approached? I would think the CDC SPHERES project would be particularly interested in encouraging open access across the world for this kind of data, especially with the rapid emergence of new SARS-CoV-2 variants that may have major

significance. From the web, I see that David Wentworth of CDC is on the GISAID Scientific Advisory Committee, could he help make this case?

On behalf of NIH (including NCBI/NLM and NIAID) I am flagging this as an important issue. I would like to work with CDC in seeking a more open approach by GISAID. I would bet that Rochelle Walensky would also support this. Can I get your advice on how this might be best approached?

Thanks for your help,

Francis

From: Bugin, Kevin [REDACTED] b6
Sent: 4/20/2021 1:30:21 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans
Flag: Follow up

Hi Francis,

This is what I know about the presentation David Kessler is giving to the WH next week:

“David will be making a presentation at the White House next week about plans for an anti-viral program. While he is there, he would like to provide an update on the ACTIV program.”

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Thanks,

Kevin

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Monday, April 19, 2021 9:02 PM
To: Bugin, Kevin <[REDACTED]> b6
Cc: Tabak, Lawrence A (NIH) <[REDACTED]> b6 Wholley, David N (NIH) <[REDACTED]> b6 Freire, Maria C (NIH) <[REDACTED]> b6 Parker, Ashley S (NIH) <[REDACTED]> b6
Subject: [EXTERNAL] TIME SENSITIVE: Need to speak about future plans

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COLL0000013443

Kevin, I am getting increasingly concerned about the path being travelled by these plans. While there have been some NIH reps taking part in your process, and no doubt they could have done a better job of informing the rest of us, I am mostly in the dark about where this is going – as are Larry Tabak, David Wholley, and Maria Freire. We were all appreciative of your presentation to the War Room last Wednesday, but the time was too short to clarify a lot of the areas of confusion.

Could you be available for a 45-minute call or Zoom with me and the folks in the cc line tomorrow at 8 AM?

Thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 9/28/2020 12:45:53 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Also as requested. Let me know if you need follow-up on any of these points.

From: Woodcock, Janet < b6 >
Sent: Sunday, September 27, 2020 3:34 PM
To: Davey Smith < b6 > Bozzette, Sam (NIH/NCATS) [E] < b6 > Teyhen, Deydre (HHS/IOS) < b6 > Adam, Stacey (FNIH) [T] < b6 > Marks, Gilbert (OS/ASPR/BARDA) (CTR) < b6 > Read, Sarah (NIH/NIAID) [E] < b6 > Lane, Cliff (NIH/NIAID) [E] < b6 > Erbeling, Emily (NIH/NIAID) [E] < b6 > Eakin, Ann (NIH/NIAID) [E] < b6 > Erica Ollmann Saphire < b6 > Stein, Peter (FDA/CDER) < b6 > Judy Currier < b6 > Kim, Peter (NIH/NIAID) [E] < b6 > Higgs, Elizabeth (NIH/NIAID) [E] < b6 > Kiley, James (NIH/NHLBI) [E] < b6 > Goff, David (NIH/NHLBI) [E] < b6 > Kara Chew < b6 >
Cc: Leyva, Jessica M. [Infectious Diseases] < b6 > Chen, Helen Q. < b6 > Wholley, David (FNIH) [T] < b6 > Bugin, Kevin (FDA/CDER) < b6 > Carver, Trea (NIH) [C] < b6 > Reich, Colleen < b6 > Lisbeth Jørgensen < b6 > Rose Li Central Account < b6 > Dana Carluccio < b6 > Elsaid, Olivia < b6 > Church, Elizabeth (NIH/NIAID) [E] < b6 > Erhardt, William (HHS/IOS) < b6 > Harrigan, Rachel (HHS/IOS) < b6 >
Subject: RE: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Thanks, very thoughtful. jw

From: Smith, David < b6 >
Sent: Sunday, September 27, 2020 2:31 PM
To: Bozzette, Sam A (NIH) < b6 > Teyhen, Deydre (OS) < b6 > Woodcock, Janet < b6 > Adam, Stacey J (NIH) < b6 > Marks, Gilbert L (OS) < b6 > Read, Sarah W (NIH) < b6 > Lane, Henry C (NIH) < b6 > Erbeling, Emily J (NIH) < b6 > Eakin, Ann E (NIH) < b6 > Erica Ollmann Saphire < b6 > Stein, Peter < b6 > Currier, Judith, M.D. < b6 > Kim, Peter S (NIH) < b6 > Higgs, Elizabeth S (NIH) < b6 > Kiley, James P (NIH) < b6 > Goff, David C (NIH) < b6 >

b6
Cc: Leyva, Jessica M. [Infectious Diseases] <b6> Chen, Helen Q. <b6>
Wholley, David N (NIH) <b6> Bugin, Kevin <b6> Carver-Roberts, Trea R (NIH)
<b6> Reich, Colleen <b6> Lisbeth Jørgensen
<b6> Rose Li Central Account <b6> Dana Carluccio
<b6> Elsaid, Olivia <b6> Church, Elizabeth S (NIH)
<b6> Erhardt, William (HHS/IOS) <b6> Harrigan, Rachel (OS)
<b6>

Subject: Re: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Hello Team

In preparation for our call I wanted to circulate some of my thoughts on this matter.

Issues

- There is no other treatment close for early COVID-19
- Untreated people often have persistent symptoms after untreated COVID-19, like chronic inflammation, fatigue, myalgia, loss of smell and taste, etc.
- Untreated people can spread within the community.
- Predictors of who will get seriously ill are imprecise and very general.
 - Younger people and those without co-morbidities can become seriously ill

Pros

The (b) (4) agent:

- Was safe in a dose range finding study
- showed virological response
 - Need standardized virology
- showed benefit to keep people out of the hospital and ER
 - The actual benefit may be smaller or larger in a well-powered study
- Multiple MAb in development – competitive environment – may impact cost and availability
 - innovation will allow for more convenient administration for agents that demonstrate activity
- Lack of other promising agents that do not need infusion.
 - (b) (4)
 -

Cons

The (b) (4) agent:

- Requires infusion
 - I think this is mainly a problem in a clinical trial. In the real world an infusion nurse can be sent to a person's home or patients can receive an infusion in the ER.
 - For example, it does not look like convalescent plasma is having a problem administering plasma in the ER.
 - Innovation of administration is likely in a competitive environment

Adjustments

- Focus only on older people with co-morbidities.
 - I think the benefit of early treatment extends beyond hospitalization and death but it is a convenient endpoint. If the agent was approved off such a trial, would it only be used in that population?

I wanted to share with you our draft of the letter to go to the DSMB for the dose change; see attached.
Talk to you soon.
davey

Davey Smith, MD, MAS

Head | Division of Infectious Diseases and Global Public Health
Professor | Department of Medicine
Co-Director | San Diego Center for AIDS Research (CFAR)
Florence Riford Seeley Chair | AIDS Research
University of California San Diego | b6
Pronouns: he, him, his

Administrative Contact:

Colleen Reich | b6
9500 Gilman Drive, La Jolla, CA 92093-0679
P. b6 | F. b6

If your research has been supported by the San Diego CFAR, please be sure to acknowledge that support in your resulting publications and presentations (AI036214). More on acknowledging CFAR support may be found at <https://cfar.ucsd.edu/en/cite-the-cfar/>.

From: Bozzette, Sam (NIH/NCATS) [E] < b6 >
Sent: Saturday, September 26, 2020 2:36 PM
To: Teyhen, Deydre (HHS/IOS) < b6 > Woodcock, Janet (FDA/CDER)
< b6 > Adam, Stacey (FNIH) [T] < b6 > Marks, Gilbert (OS/ASPR/BARDA) (CTR)
< b6 > Read, Sarah (NIH/NIAID) [E] < b6 > Lane, Cliff (NIH/NIAID) [E]
< b6 > Erbeling, Emily (NIH/NIAID) [E] < b6 > Eakin, Ann (NIH/NIAID) [E]
< b6 > Erica Ollmann Saphire < b6 > Stein, Peter (FDA/CDER) < b6 >
Currier, Judith, M.D. < b6 > Smith, David < b6 > b6
< b6 > b6 < b6 > b6
< b6 > Higgs, Elizabeth (NIH/NIAID) [E] < b6 > Kiley, James (NIH/NHLBI) [E]
< b6 > Goff, David (NIH/NHLBI) [E] < b6 >
Cc: Leyva, Jessica M. [Infectious Diseases] < b6 > Chen, Helen Q. < b6 >
Wholley, David (FNIH) [T] < b6 > Bugin, Kevin (FDA/CDER) < b6 > Carver, Trea
(NIH) [C] < b6 > Reich, Colleen < b6 > Lisbeth Jørgensen
< b6 > Rose Li Central Account < b6 > Dana Carluccio
< b6 > Elsaid, Olivia < b6 > Church, Elizabeth (NIH/NIAID) [E]
< b6 > Erhardt, William (HHS/IOS) < b6 > Harrigan, Rachel (HHS/IOS)
< b6 >
Subject: Re: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Yes

From: "Teyhen, Deydre (HHS/IOS)" < b6 >
Date: Saturday, September 26, 2020 at 1:48:43 PM
To: "Bozzette, Sam (NIH/NCATS) [E]" < b6 > "Woodcock, Janet (FDA/CDER)"
< b6 > "Adam, Stacey (FNIH) [T]" < b6 > "Marks, Gilbert (OS/ASPR/BARDA)"

(CTR)" < b6 "Read, Sarah (NIH/NIAID) [E]" < b6 "Lane, Cliff (NIH/NIAID) [E]"
< b6 "Erbelding, Emily (NIH/NIAID) [E]" < b6 "Eakin, Ann (NIH/NIAID) [E]"
< b6 "Erica Ollmann Sapphire" < b6 "Stein, Peter (FDA/CDER)" < b6
"Judy Currier" < b6 "Davey Smith" < b6 "Kim, Peter (NIH/NIAID) [E]"
< b6 " b6 < b6 " b6
< b6 "Higgs, Elizabeth (NIH/NIAID) [E]" < b6 "Kiley, James (NIH/NHLBI) [E]"
< b6 "Goff, David (NIH/NHLBI) [E]" < b6
Cc: "Leyva, Jessica M. [Infectious Diseases]" < b6 "Chen, Helen Q." < b6
"Wholley, David (FNIH) [T]" < b6 "Bugin, Kevin (FDA/CDER)" < b6 "Carver, Trea
(NIH) [C]" < b6 "Reich, Colleen" < b6 "Lisbeth Jørgensen"
< b6 "Rose Li Central Account" < b6 "Dana Carluccio"
< b6 "Elsaid, Olivia" < b6 "Church, Elizabeth (NIH/NIAID) [E]"
< b6 "Erhardt, William (HHS/IOS)" < b6 "Harrigan, Rachel (HHS/IOS)"
< b6

Subject: RE: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Sam,

In regards to your comment below, would focusing on those coming to an emergency room due to COVID symptoms that would below the threshold for hospitalization – or – those with multiple risk factors for severe disease address your concerns outlined below?

STAY FIT!

COL Deydre Teyhen

COL Deydre S. Teyhen, DPT, PhD | Operation Warp Speed | Office: b6 | Cellular: b6 | HHS E-mail: b6 | DoD E-mail: b6 |

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From: Bozzette, Sam (NIH/NCATS) [E] < b6
Sent: Saturday, September 26, 2020 11:21 AM
To: Woodcock, Janet (FDA/CDER) < b6 Adam, Stacey (FNIH) [T] < b6 Marks, Gilbert (OS/ASPR/BARDA) (CTR) < b6 Read, Sarah (NIH/NIAID) [E] < b6 Lane, Cliff (NIH/NIAID) [E] < b6 Erbelding, Emily (NIH/NIAID) [E] < b6 Eakin, Ann (NIH/NIAID) [E] < b6 Erica Ollmann Sapphire < b6 Stein, Peter (FDA/CDER) < b6 Judy Currier < b6 Davey Smith < b6 Kim, Peter (NIH/NIAID) [E] < b6 b6 b6 Higgs, Elizabeth (NIH/NIAID) [E] < b6 Kiley, James (NIH/NHLBI) [E] < b6 Goff, David (NIH/NHLBI) [E] < b6
Cc: Leyva, Jessica M. [Infectious Diseases] < b6 Chen, Helen Q. < b6 Wholley, David (FNIH) [T] < b6 Bugin, Kevin (FDA/CDER) < b6 Carver, Trea (NIH) [C] < b6 Reich, Colleen < b6 Lisbeth Jørgensen < b6 Rose Li Central Account < b6 Dana Carluccio < b6 Elsaid, Olivia < b6 Church, Elizabeth (NIH/NIAID) [E] < b6 Teyhen, Deydre (HHS/IOS) < b6 Erhardt, William (HHS/IOS)

< b6 Harrigan, Rachel (HHS/IOS) < b6
Subject: Re: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Really hate to say it, but hard to see how an outpatient infusion with a net modest effect will make much of a dent in public health. The number needed to treat in order to prevent one hospitalization will likely be large and the are logistics daunting.

From: "Woodcock, Janet" b6
Date: Saturday, September 26, 2020 at 11:09:28 AM
To: "Adam, Stacey (FNIH) [T]" b6 >, "Marks, Gilbert (OS/ASPR/BARDA) (CTR)" b6 >, "Bozzette, Sam (NIH/NCATS) [E]" b6 >, "Read, Sarah (NIH/NIAID) [E]" < b6 "Lane, Cliff (NIH/NIAID) [E]" b6 >, "Erbelding, Emily (NIH/NIAID) [E]" < b6 "Eakin, Ann (NIH/NIAID) [E]" b6 >, "Erica Ollmann Sapphire" < b6 "Stein, Peter (FDA/CDER)" < b6 "Judy Currier" b6 >, "Davey Smith" < b6 "Kim, Peter (NIH/NIAID) [E]" b6 >, "Higgs, Elizabeth (NIH/NIAID) [E]" < b6 "Kiley, James (NIH/NHLBI) [E]" b6 >, "Goff, David (NIH/NHLBI) [E]" b6
Cc: "Leyva, Jessica M. [Infectious Diseases]" < b6 "Chen, Helen Q." < b6 "Wholley, David (FNIH) [T]" < b6 "Bugin, Kevin (FDA/CDER)" < b6 "Carver, Trea (NIH) [C]" < b6 >, "Reich, Colleen" < b6 >, "Lisbeth Jørgensen" b6 >, "Rose Li Central Account" <FNIH@roseliassociates.com>, "Dana Carluccio" < b6 "Elsaid, Olivia" b6 >, "Church, Elizabeth (NIH/NIAID) [E]" < b6 "Teyhen, Deydre (HHS/IOS)" b6 >, "Erhardt, William (HHS/IOS)" b6 >, "Harrigan, Rachel (HHS/IOS)" < b6
Subject: RE: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

I would like to contribute some additional thoughts now that we have the Lilly data in hand and we have experience with these trials.

With respect to ACTIV 2, I have two thoughts.

First, although (b) (4) tried hard to recruit at-risk persons, the vast majority in the placebo group got better eventually on their own. Undoubtedly, if a shortening of illness and suffering can be demonstrated, then there would be a benefit to this population. But with a prolonged IV infusion, or any IV infusion, it raises the question "Is the juice worth the squeeze"? I believe we should think hard about studying a therapy in possibly 1500 people that is not a practical outpatient solution. This is not to say I think we should halt the trial or anything, I really think we should evaluate where we are going with this. Is it possible to re-design to recruit only high risk people to Stage 2 of the protocol to make the administration more worth the effort of infusion? I'd say any group with a greater than 10-15% hospitalization rate would truly warrant any intervention, since some of those people will go on to have very severe disease but of course that number is arbitrary. Can we talk more to (b) (4) about a injectable formulation and design a reasonable transition to that, while continuing to study the IV infusion?

(b) (4)

With respect to ACTIV 3, site activation is still a problem. I believe we should take the survey results to heart and think about how we can make life easier for investigators. I also think we should work very hard to get non-big-medical-center sites up with subinvestigators or other ways. There is much competition for patients at the big centers while thousands of people are hospitalized at community hospitals, many of which have relationships with a teaching hospital and are not running protocols. OWS recently spoke to a sponsor that successfully recruited their trial using the strategy of community hospital sites, according to them. Regardless, we will not reach our objectives unless site activation picks up substantially.





Thanks. Looking forward to more discussion. jw

From: Adam, Stacey (FNIH) [T] < b6 >
Sent: Friday, September 25, 2020 4:34 PM
To: Woodcock, Janet < b6 > Marks, Gilbert L (OS) < b6 > Bozzette, Sam A (NIH) < b6 > Read, Sarah W (NIH) < b6 > Lane, Henry C (NIH) < b6 > Erbelding, Emily J (NIH) < b6 > Eakin, Ann E (NIH) < b6 > Erica Ollmann Saphire < b6 > Stein, Peter < b6 > Judy Currier < b6 > Davey Smith < b6 > Kim, Peter S (NIH) < b6 > b6 < b6 > Higgs, Elizabeth S (NIH) < b6 > Kiley, James P (NIH) < b6 > Goff, David C (NIH) < b6 >
Cc: Leyva, Jessica M. [Infectious Diseases] < b6 > Chen, Helen Q. < b6 > Wholley, David N (NIH) < b6 > Bugin, Kevin < b6 > Carver-Roberts, Trea R (NIH) < b6 > Reich, Colleen < b6 > Lisbeth Jørgensen < b6 > Rose Li Central Account < b6 > Dana Carluccio < b6 > Elsaid, Olivia < b6 > Church, Elizabeth S (NIH) < b6 > Teyhen, Deydre (OS) < b6 > Erhardt, William (HHS/IOS) < b6 > Harrigan, Rachel (OS) < b6 >
Subject: Summary from ACTIV-2/-3 Trial Oversight Committee Meeting 09/23/2020

Dear ACTIV-2/3 Trial Oversight Committee,

Please find attached the summary from our meeting on Wednesday. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: b6 | Mobile: b6
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
   

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Gadbois, Ellen (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0243D1D6E6F248268D2EDEC566C26C2A-GADBOISEL]
Sent: 2/17/2021 9:59:10 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
CC: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: biospecimen prioritization committee--how could we implement?
Attachments: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Hi Patti,
Thanks for the quick chat this afternoon. Here's the issue in a nutshell:

Cliff Lane wants to establish a biospecimen prioritization committee to handle requests to use biospecimens collected in the ACTIV trials. David Wholly at FNIH sent Michelle the attached slides describing the plan and a message below. FNIH does not want to run this—they expect NIH to implement. However, (b) (5)
(b) (5)

So here are the other paths I'm thinking about:

- 1) (b) (5)
- 2)
- 3)

Any ideas you and/or Claire have are welcome. Happy to get on the phone again.

Thanks,
Ellen

From: Wholley, David (FNIH) [T] b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] b6
Cc: Adam, Stacey (FNIH) [T] b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,
I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)
(b) (5)

(b) (5)

Thanks

Sent: 2/26/2021 1:54:44 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f38f3da2fb3498f838fd8538dea77f4-brandtp]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

That's weird.

From: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Sent: Friday, February 26, 2021 8:51 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

There's no number in the Skype for you – what's the best # for me to call?

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 >
Sent: Friday, February 26, 2021 8:49 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK ready now

From: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Sent: Friday, February 26, 2021 8:37 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

OK – just email me when you are ready

From: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 >
Sent: Friday, February 26, 2021 8:36 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

I just got off a call so need about 5 minutes to review, but then yes

From: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Sent: Friday, February 26, 2021 8:35 AM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Are you available for a quick skype?

From: Culp, Michelle (NIH/OD) [E] <[REDACTED] b6 >
Sent: Thursday, February 25, 2021 4:58 PM
To: Gadbois, Ellen (NIH/OD) [E] <[REDACTED] b6 > Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Ellen and Patti,

I took a stab and developing an options document. I stole text from the ACTIV slides to give some background on the ACTIV Biospecimen Prioritization Committee (ABPC). I hope I got the group management description right. The pros and cons are not fully completed.

-Michelle

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, February 25, 2021 12:06 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [REDACTED] b6 >; Martin, Ann (NIH/OD) [E] [REDACTED] b6 >
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

What a colorful email! One thing added in blue on WGs lifespan. I have an ACD WG established in 2009 and technically still around, although they have not met for some years I as haven't needed them to.

From: Brandt Hansberger, Patricia (NIH/OD) [E] [REDACTED] b6 >
Sent: Thursday, February 25, 2021 11:58 AM
To: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6 ; Martin, Ann (NIH/OD) [E] [REDACTED] b6
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED]
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi-see responses in green

From: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, February 25, 2021 10:18 AM
To: Martin, Ann (NIH/OD) [E] <[REDACTED] b6> Brandt Hansberger, Patricia (NIH/OD) [E] [REDACTED] b6
Cc: Culp, Michelle (NIH/OD) [E] [REDACTED] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

My comments below in BLUE.

From: Martin, Ann (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, February 25, 2021 9:10 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] <[REDACTED] b6>
Cc: Gadbois, Ellen (NIH/OD) [E] [REDACTED] b6 >; Culp, Michelle (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
2:30 works best for me today, if that still works on your end.

For your consideration in the meantime, [REDACTED] (b) (5). We are not aware of committees that fall into that "operational" category in the absence of a statutory basis for such a role. It is hard for me to see "operational" as an option for the biospecimen committee. It is correct that the sharing of information in a group setting between federal officials and experts does not implicate FACA. The important aspect in such a scenario, however, is that it be grounded on an exchange of information. The non-government participants would not have an advisory role. This is different than an "operational" committee within the meaning of "operational" for purposes of the FACA regulations. It doesn't seem that the "information exchange" setting will suit NIH's/ACTIV's needs here, but I would be happy to explore this further with you.

I have also made a few notes below in red.

Happy to discuss this afternoon.

Thanks,
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Wednesday, February 24, 2021 7:55 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Gadbois, Ellen (NIH/OD) [E] <b6>; Culp, Michelle (NIH/OD) [E] b6; Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Ann! Tara and Larry want us to lay out all the options in one email which I am working on with Ellen and she would like to have one more chat and wants to understand more how DSMB's work in particular. I took a crack at starting something (see directly below) and Ellen is going to start wordsmithing this tomorrow. Our goal is to keep this as concise as possible.

I know this is short notice, but wondering if you were available any of the times below tomorrow?

- 9:00
- Noon
- 2:30

FACA Options:

(b) (5)



(b) (5)

Non-FACA Options:

(b) (5)

(b) (5)

From: Martin, Ann (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 3:55 PM
To: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Hi, Patti,
Thanks for the info below. I would be glad to talk with you and Claire about this on Monday. Would 11:30 or later work ok?
Hope you are doing well!
Ann

Ann D. Martin
Senior Attorney, Office of the General Counsel
HHS, PHD, NIH Branch
31 Center Drive, Bldg. 31, Rm. 2B-50
Bethesda, MD 20892
b6 (main)
b6

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From: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 2:07 PM
To: Martin, Ann (NIH/OD) [E] b6
Cc: Brandt Hansberger, Patricia (NIH/OD) [E] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Good afternoon. I am working with Claire on an ACTIV issue. Per the email trail below, (b) (5)

(b) (4) The committee would be comprised of ACTIV trial team members, academic, and industry representatives who would set review and prioritization criteria, assess biospecimen requests, and recommend which ones should be reviewed by an oversight committee (see slide 6). Claire and I had a conversation with Ellen Gadbois and Michelle Culp yesterday about possible options if NIH were to form such a committee. The email Ellen sent to LAT below is based on that conversation.

The email exchange contains several ideas and Claire wanted your thoughts on the following idea from Tara:

(b) (5)

I just had a chat with Claire, and this wouldn't be a subcommittee or a workgroup of a full committee; it seems like something different. Claire wants to know if Tara's idea raised any FACA issues, or any other for that matter.

It might be easier to have a conversation to talk this through and Claire is very flexible for Monday. Do you have any time in your schedule on Monday for an informal chat?

GADB0000004383

Thanks!
Patti

From: Harris, Claire (NIH/OD) [E] [REDACTED] b6
Sent: Friday, February 19, 2021 11:41 AM
To: Brandt Hansberger, Patricia (NIH/OD) [E] [REDACTED] b6
Cc: Harris, Claire (NIH/OD) [E] [REDACTED] b6
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

Patti,

Would you connect with Ann Martin on the following:

[REDACTED] b5

I will respond to Tara on the 2nd paragraph.

Thx

From: Schwetz, Tara (NIH/OD) [E] <[REDACTED]> b6
Sent: Friday, February 19, 2021 11:38 AM
To: Harris, Claire (NIH/OD) [E] [REDACTED] b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Yes, absolutely.

So, I view those options I mentioned as two separate approaches. That said, [REDACTED] (b) (5)
[REDACTED] We normally form working groups with 1 or 2 members from the parent committee and the rest are folks who are not. They are not invited as SGEs. For example, that's how all of the ACD WGs function (<https://acd.od.nih.gov/working-groups.html>). I was thinking something like that as a second option, in addition to considering the internal committee with consulting-type option.

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: [REDACTED] b6 | M: [REDACTED] b6



From: "Harris, Claire (NIH/OD) [E]" [REDACTED] b6 >
Date: Friday, February 19, 2021 at 8:31 AM
To: Tara Schwetz [REDACTED] b6
Cc: "Harris, Claire (NIH/OD) [E]" [REDACTED] b6
Subject: RE: for LT consideration: ACTIV biospecimen committee options/need guidance

Tara,

What you describe could work but I feel more comfortable running it by OGC. Is that ok?

Yes, we could establish a subcommittee (b) (5) (b) (5)

(b) (5) get approval and appoint the subcommittee members as SGEs. As you know, this is a long process.

Best,

Claire

From: Schwetz, Tara (NIH/OD) [E] b6
Sent: Friday, February 19, 2021 1:35 AM
To: Harris, Claire (NIH/OD) [E] < b6
Subject: Re: for LT consideration: ACTIV biospecimen committee options/need guidance

Thanks for the heads up. My first thought was to try to do something akin to option 3, but it sounds like there isn't a way around it. (b) (5)
(b) (5)

Best,

Tara A. Schwetz, PhD
Associate Deputy Director, NIH
A: Building 1, Room 138
P: b6 | M: b6



From: "Harris, Claire (NIH/OD) [E]" < b6
Date: Thursday, February 18, 2021 at 5:46 PM
To: Tara Schwetz b6 >
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI – More from my previous email.

From: Gadbois, Ellen (NIH/OD) [E] b6
Sent: Thursday, February 18, 2021 5:14 PM
To: Harris, Claire (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E]
Subject: FW: for LT consideration: ACTIV biospecimen committee options/need guidance

FYI. I hope I got this mostly right. I wanted to get a message over the transom now in case this comes up in one of the ACTIV morning calls—I'm not sure if they meet tomorrow or not. Any mistakes are mine and you can blame me!

From: Gadbois, Ellen (NIH/OD) [E]
Sent: Thursday, February 18, 2021 5:12 PM
To: Tabak, Lawrence (NIH/OD) [E] b6
Cc: Culp, Michelle (NIH/OD) [E] b6
Subject: for LT consideration: ACTIV biospecimen committee options/need guidance

Dear Larry,

David Wholley asked Michelle and myself to consider the draft plan that FNIH put together for a committee structure to manage requests for use of ACTIV biospecimens. We believe Cliff Lane is encouraging the formation of this group. I'm attaching the slides David sent us for context (see slide 6 in particular).

Michelle and I understand that (b) (5) to take this on, so we were looking at how NIH could implement some kind of centralized system of review of biospecimen requests that includes both NIH staff and non-Federal participants (industry and academic reps). We have informally spoken to Claire Harris and Patti Brandt-Hansberger to see if a committee would fall under FACA rules. (b) (5)

(b) (5)

We briefly explored other non-FACA models, but those have problems too, listed below:

- 1) (b) (5)
- 2)
- 3)
- 4)
- 5)

In sum, we're not sure where to go with this idea. Please advise on whether you think there is a good direction to explore further or people to talk to.

Thanks,
Ellen

Ellen L. Gadbois, Ph.D.
Lead, Emerging Biotechnology Policy
Office of Science Policy
Office of the Director
National Institutes of Health
Building 1 Suite 218
voice: b6
fax: 301-402-0280

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,

I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

(b) (5)

(b) (5)

Thanks

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 2/12/2021 4:35:08 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

David,

I am not a FACA expert but I understand your concern. In my read of the slides you provided, the committee includes feds, academics and industry experts. Responsibilities say "independent review and an initial assessment" and "develop recommendations". The role of making recommendations sounds similar to how a DSMB makes *recommendations* to NIH (never *advisory* or it becomes a FACA). Then NIH is responsible for taking an action or not. But like a DSMB, I'd recommend all members of the biospecimen committee disclose any real or potential conflicts and someone determine if those conflicts need to be mitigated or if the person is too conflicted to participate. The committee governance should also consider if members should sign a non-disclosure or confidentiality agreement.

Some other thoughts: What is the motivation for including industry? Do they have a unique expertise or perspective?

Let me know if I should find a FACA expert to weigh in on this. I am taking leave tomorrow, but will check email periodically.

Best,
Michelle

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, February 11, 2021 10:43 PM
To: Culp, Michelle (NIH/OD) [E] <[REDACTED]> b6
Cc: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Subject: ACTIV_TX-Clinical_Biospecimen Priorization Committee Overview_DRAFT_20210202 SR-sja-AS.pptx

Michelle,

I could use your help on something. As you may recall, we were approached by Cliff Lane and then some other ACTIV trial team folks to figure out how best to coordinate the use of samples from ACTIV trials to solve questions of broad scientific interest. Stacey ran a team that looked at the best process to make these decisions. (b) (5)

(b) (5)

(b) (5)

Thanks

Sent: 5/15/2020 12:22:10 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: (b) (5)

Hi David,

See note below from Janet. (b) (5) (b) (5)

(b) (5)

FC

From: Woodcock, Janet < (b) (5) >
Sent: Thursday, May 14, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) >
Subject: (b) (5)

(b) (5)

I will be there tomorrow, despite my staunch resistance, so maybe I'll see you at the announcement. jw

Sent: 5/20/2020 2:25:53 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: Monoclonal antibody protocols through ACTIV

My ACTIV e-mail inbox is buzzing this morning. See note below from Janet.

I would certainly agree that (b) (5). I'm not entirely sure I understand the last sentence of her first paragraph.

From: Woodcock, Janet <(b) (5)>
Sent: Wednesday, May 20, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] <(b) (5)>
Subject: Monoclonal antibody protocols through ACTIV

Francis, a couple points. I'm sure you are being kept up to speed by the FNIH folks, (b) (5)
(b) (5)

(b) (5). So I'm OK with voting on candidates etc but need to have a discussion on strategy.

Second, I spoke to Mike Kurilla about the NIH trial portfolio on COVID19 disease. In a nutshell, there is not an inventory. We offered to work with him on an inventory we have and (b) (5)
(b) (5) we don't always know what people are working on.

jw

Sent: 5/20/2020 6:37:44 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Monoclonal antibody protocols through ACTIV

Hi Chris,

Aha, now I think I get it. (b) (5)

I'd be glad to send the request to the IC Directors – but it would help me to have a draft that would capture the right features.

FC

From: Austin, Christopher (NIH/NCATS) [E] < > b6
Sent: Wednesday, May 20, 2020 1:31 PM
To: Collins, Francis (NIH/OD) [E] < > b6
Cc: Wholley, David (FNIH) [T] < > b6
Subject: RE: Monoclonal antibody protocols through ACTIV

Hi Francis,

Simple question, complex answer, since the information needed is nonpublic.

- (b) (5)
- 1.
 - 2.
 - 3.

If you would rather not send out the request to the ICDs, I would be glad to do so with your imprimatur, including working out answers to the thorny information sharing questions (for example, who gets to see the data? for what reason? how to we prevent potential applicants from seeing the trials being planned if the data are shared with ACTIV?).

Apologies for the long answer. Bottom line: an inventory of trials already recruiting (CT.gov) is being created but is not yet extant. An inventory of trials being planned would require a different more labor-intensive effort with the ICDs. I am glad to do that. Just let me know if you'd like me to do so.

Chris

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, May 20, 2020 11:05 AM
To: Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6
Cc: Wholley, David (FNIH) [T] [REDACTED] b6 >
Subject: FW: Monoclonal antibody protocols through ACTIV

Hey Chris,

Please see paragraph 2. [REDACTED] (b) (5)
[REDACTED] (b) (5)

FC

From: Woodcock, Janet [REDACTED] b6 >
Sent: Wednesday, May 20, 2020 10:16 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Monoclonal antibody protocols through ACTIV

Francis, a couple points. I'm sure you are being kept up to speed by the FNIH folks, [REDACTED] (b) (5)
[REDACTED] (b) (5)

[REDACTED] (b) (5) So I'm OK with voting on candidates etc but need to have a discussion on strategy.

Second, I spoke to Mike Kurilla about the NIH trial portfolio on COVID19 disease. In a nutshell, there is not an inventory. We offered to work with him on an inventory we have and [REDACTED] (b) (5)
[REDACTED] (b) (5) we don't always know what people are working on.

jw

Sent: 6/15/2020 6:54:59 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: Next wave of antivirals

FYI. I assume that the (b) (5)
Right?

Do you know (b) (5)

FC

From: Woodcock, Janet < (b) (5) >
Sent: Monday, June 15, 2020 2:05 PM
To: Collins, Francis (NIH/OD) [E] < (b) (5) >
Subject: RE: Next wave of antivirals

Well there are several issues to consider. First, (b) (5)
(b) (5) Second, I know NIAID (b) (5)
(b) (5)
(b) (5) I'd
certainly be interested in exploring. I know (b) (5)
(b) (5) For immunomodulators we need to discuss more. RECOVERY is reading out a result tomorrow and we will need to discuss that. Happy to have a conversation. jw

From: Collins, Francis (NIH/OD) [E] (b) (5) >
Sent: Monday, June 15, 2020 1:11 PM
To: Woodcock, Janet (b) (5)
Cc: Wholley, David N (NIH) (b) (5)
Subject: Next wave of antivirals

Hi Janet,

The Therapeutics-Clinical Working Group of ACTIV is now well into the process of prioritizing the next wave of small molecules, including antivirals. They are planning for these to be rolled into a new *de novo* master protocol, and this trial would become ACTIV-5. I know that your budget, approved by the OWS Board, (b) (5)
(b) (5) Are you OK with ACTIV proceeding to plan this out, including the master protocol and the clinical trial network that could carry it out? Or do you have other plans such as

the I-SPY approach? I wouldn't want the hard working folks at ACTIV to get surprised about the way this might emerge, so I thought I'd best inquire about this now.

David Wholley and I would be glad to talk by phone about this if that would be helpful.

Best, Francis

Sent: 6/17/2020 4:52:39 PM
To: Woodcock, Janet [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Next wave of antivirals

Hi Janet,

As you heard in the ACTIV ExComm presentation, WAVE 2 is prioritizing compounds that could go quickly into clinical trials, with ACTIV-5 planned to get underway by August. So hopefully this fits the OWS plans for deliverables by early winter.

It would be really good for the ACTIV team to have a sense from you about two things:

- 1) [REDACTED] (b) (5)
- 2) [REDACTED]

It would be really helpful for the Therapeutics-Clinical Working Group to have a sense about the answer to these two questions. They are working incredibly hard right now, and I want to be sure they are not doing so under inaccurate assumptions about the outcome of their work.

Thanks, Francis

From: Woodcock, Janet <[REDACTED] b6>
Sent: Monday, June 15, 2020 2:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Subject: RE: Next wave of antivirals

Well there are several issues to consider. First, [REDACTED] (b) (5)
[REDACTED] Second, I know NIAID [REDACTED] (b) (5)
[REDACTED]
[REDACTED] I'd
certainly be interested in exploring. I know [REDACTED] (b) (5)
[REDACTED] For immunomodulators we need to discuss more. RECOVERY is reading out a result tomorrow and we will need to discuss that. Happy to have a conversation. jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Monday, June 15, 2020 1:11 PM
To: Woodcock, Janet [REDACTED] b6 >
Cc: Wholley, David N (NIH) [REDACTED] b6
Subject: Next wave of antivirals

Hi Janet,

The Therapeutics-Clinical Working Group of ACTIV is now well into the process of prioritizing the next wave of small molecules, including antivirals. They are planning for these to be rolled into a new *de novo* master protocol, and this trial would become ACTIV-5. I know that your budget, approved by the OWS Board, includes \$175M for things like this – but I don't think you and I have talked much about the details. Are you OK with ACTIV proceeding to plan this out,

including the master protocol and the clinical trial network that could carry it out? Or do you have other plans such as the I-SPY approach? I wouldn't want the hard working folks at ACTIV to get surprised about the way this might emerge, so I thought I'd best inquire about this now.

David Wholley and I would be glad to talk by phone about this if that would be helpful.

Best, Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E998E83770CFC7EE770-TABAKL]
Sent: 8/31/2020 3:07:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners
Attachments: OWS - Connecting the Trials.pptx; Rise Above COVID Branding POV 8.17.20 FINAL.pdf

Flag: Follow up

fyi

From: "Bugin, Kevin" <[REDACTED]> b6
Date: Monday, August 31, 2020 at 11:06 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6 "Wholley, David (FNIH) [T]" <[REDACTED]> b6
Cc: Janet Woodcock <[REDACTED]> b6 "Erhardt, William (HHS/IOS)" <[REDACTED]> b6
Subject: FW: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

Larry, David,
Please see attached for a couple of work in progress documents that describe the Rise Above COVID effort that Janet mentioned. We can discuss further when we meet. Thanks,

Kevin

From: Woodcock, Janet [REDACTED] b6
Sent: Monday, August 31, 2020 9:18 AM
To: Tabak, Lawrence A (NIH) <[REDACTED]> b6 Billet, Courtney R (NIH) [REDACTED] b6 Burklow, John T (NIH) [REDACTED] b6; Myles, Renate H (NIH) [REDACTED] b6; Johnson, Lenora E (NIH) [REDACTED] b6; Schmitt, Clare K (NIH) [REDACTED] b6; Bugin, Kevin <[REDACTED]> b6
Cc: Austin, Christopher P (NIH) [REDACTED] b6; Gibbons, Gary H (NIH) <[REDACTED]> b6 Lane, Henry C (NIH) [REDACTED] b6; Patterson, Amy (NIH) [REDACTED] b6; Perez-Stable, Eliseo J (NIH) [REDACTED] b6; Burrus-Shaw, Cyndi R (NIH) [REDACTED] b6; McManus, Ayanna L (NIH) [REDACTED] b6; Simon, Dina M (NIH) [REDACTED] b6; Wood, Gretchen S (NIH) [REDACTED] b6
Subject: RE: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

We at OWS are also seeing a proposal for "Rise Above COVID" that would be pan-trials. Need to make sure we merge these efforts and don't trip over each other. jw

From: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6
Sent: Monday, August 31, 2020 8:46 AM
To: Woodcock, Janet [REDACTED] b6; Billet, Courtney R (NIH) [REDACTED] b6; Burklow, John T (NIH) [REDACTED] b6; Myles, Renate H (NIH) <[REDACTED]> b6; Johnson, Lenora E (NIH) [REDACTED] b6; Schmitt, Clare K (NIH) [REDACTED] b6
Cc: Austin, Christopher P (NIH) [REDACTED] b6; Gibbons, Gary H (NIH) <[REDACTED]> b6 Lane, Henry C (NIH) [REDACTED] b6; Patterson, Amy (NIH) [REDACTED] b6; Perez-Stable, Eliseo J (NIH) [REDACTED] b6; Burrus-Shaw, Cyndi R (NIH) [REDACTED] b6; McManus, Ayanna L (NIH) [REDACTED] b6; Simon, Dina M (NIH) [REDACTED] b6; Wood, Gretchen S (NIH) [REDACTED] b6

< b6

Subject: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

Importance: High

Colleagues,

Francis hopes to meet with you (or your designee) today (or tomorrow at the latest) to discuss approaches for a general "campaign" to encourage people to become our research partners in the many Covid-19 trials. This needs to be done quickly and in a way that does not compete one trial versus another.

I would appreciate any flexibility you may offer in your schedule to allow us to meet today or tomorrow. If I have left off key communication staff members, please include them in the meeting invite.

Best wishes,
Larry

COLL0000010087

Sent: 1/14/2021 2:31:18 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: FW: virus variants

See very encouraging message below from Janet. I don't want to appear to have ignored the SCIRAM vs. ACTIV discussion, but here's a real chance to get the ACTIV priorities funded for the next year.

John and Joe, has there been

From: Woodcock, Janet <[REDACTED]> b6
Sent: Thursday, January 14, 2021 9:23 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: virus variants

Seems Moncef is out of the loop. I would be glad to prevail upon HHS to try and get this funded in the next few days. Critically needed. FDA is really interested and could have a big role to play if we have to switch epitopes. Seems like I can't join the Exec Comm now, but maybe you and I could touch base.

This would be approved thru HHS not thru the OWS mechanism, but we've been doing a lot of the funding this way recently, as GEN Perna does not want to sign things outside his remit. Moncef has always been a contractor so he would endorse things but not implement.

Let me know and I can get a funding memo going. This is very urgent. jw

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6 >
Sent: Wednesday, January 13, 2021 10:04 PM
To: Woodcock, Janet [REDACTED] b6
Cc: Wholley, David N (NIH) <[REDACTED]> b6
Subject: RE: virus variants

Hi Janet,

Thanks for reaching out. Yes, I have been somewhat obsessed about the need for ACTIV to organize a coordinated plan to assess the functional consequences (to therapeutics and vaccines) of emerging mutations in SARS-CoV-2. That would include defining the critical assays that need to be done, identifying those who can do them quickly, avoiding duplication, and making sure all of the data is shared immediately. Industry has embraced this. Joe Menetski led an effort of the Preclinical Working Group that came up with a five-point plan – a one year version of that is attached, though this will clearly need to be in place for longer than a year. As to your questions about who is involved in the ACTIV plan, Ann Eakin from NIAID and Karl Erlandson from BARDA, who I understand are the primary leaders on the OWS testing effort, were on the proposal development team with Joe. Joe tried to also involve Tim Stenzel from FDA, who was personally recommended for this by Peter Marks at CBER, but Tim has seemed somewhat disinterested.

From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/27/2020 1:19:21 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: IAVI and Merck Announce Collaboration on COVID-19 Vaccine

Tony, Francis,

While not participating in the actual contract negotiations, I am recently invited to participate in BARDA "Product Coordination Team" calls where these items are discussed for (b) (4), (b) (5)

(b) (4), (b) (5)

(b) (4), (b) (5)

Can keep you apprised.

John

From: Fauci, Anthony (NIH/NIAID) [E] < b6 >
Sent: Tuesday, May 26, 2020 8:59 PM
To: Collins, Francis (NIH/OD) [E] < b6 > Mascola, John (NIH/VRC) [E] < b6 > Lane, Cliff (NIH/NIAID) [E] < b6 > Wholley, David (FNIH) [T] < b6 > Freire, Maria (FNIH) [T] < b6 > Austin, Christopher (NIH/NCATS) [E] < b6 > Anderson, James (NIH/OD) [E] < b6 > Tabak, Lawrence (NIH/OD) [E] < b6 > Parker, Ashley (NIH/OD) [E] < b6 >
Subject: RE: IAVI and Merck Announce Collaboration on COVID-19 Vaccine

Would be interesting to learn (b) (5)

From: Collins, Francis (NIH/OD) [E] b6
Sent: Tuesday, May 26, 2020 8:47 PM
To: Fauci, Anthony (NIH/NIAID) [E] b6 ; Mascola, John (NIH/VRC) [E] b6 ; Lane, Cliff (NIH/NIAID) [E] b6 ; Wholley, David (FNIH) [T] b6 ; Freire, Maria (FNIH) [T] b6 ; Austin, Christopher (NIH/NCATS) [E] b6 ; Anderson, James (NIH/OD) [E] b6 ; Tabak, Lawrence (NIH/OD) [E] b6 ; Parker, Ashley (NIH/OD) [E] b6
Subject: FW: IAVI and Merck Announce Collaboration on COVID-19 Vaccine

Interesting response from Gary....

From: Disbrow, Gary (OS/ASPR/BARDA) <[REDACTED]> b6
Sent: Tuesday, May 26, 2020 5:34 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: IAVI and Merck Announce Collaboration on COVID-19 Vaccine

Francis,

As of today, [REDACTED] (b) (4), (b) (5)
[REDACTED] (b) (4), (b) (5)
[REDACTED] (b) (4), (b) (5)
[REDACTED] (b) (4), (b) (5)
[REDACTED] (b) (4), (b) (5)
(b) (4), I am happy to share more information and we move forward (b) (4), (b) (5)

Gary

Gary L. Disbrow Ph.D.
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: [REDACTED] b6
Mobile: [REDACTED] b6
Fax: 202-205-0873
email: [REDACTED] b6

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Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Tuesday, May 26, 2020 5:05 PM
To: Disbrow, Gary (OS/ASPR/BARDA) [REDACTED] b6
Subject: IAVI and Merck Announce Collaboration on COVID-19 Vaccine

Hi Gary,

I saw this announcement and was glad to see Merck moving forward with the VSV vaccine. [REDACTED] (b) (5)
[REDACTED] (b) (5)
[REDACTED] (b) (5) .. Is that something you can share?

Francis

APAR0000028532

Sent: 3/3/2021 5:57:58 PM
To: Bugin, Kevin <b6>
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Kevin,

Thank you for clarifying. Francis briefly heard about this and wanted to know more. Do you have the roster of participants for the research response group? How long have they been meeting and who are the lead POCs?

Ashley

From: Bugin, Kevin <b6>
Sent: Wednesday, March 3, 2021 12:49 PM
To: Parker, Ashley (NIH/OD) [E] <b6>
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Ashley,

That effort is part of the USG COVID-19 Response Research sub-team of the Therapeutics side of the response. It is not part of the lessons learned. We are nearing the end of support for the current portfolio of USG Response therapeutics and the sub-team is looking at that portfolio to identify gaps and future priorities.

Kevin

From: Parker, Ashley (NIH/OD) [E] <b6>
Sent: Wednesday, March 3, 2021 11:15 AM
To: Bugin, Kevin <b6>
Subject: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin,

I hope all is well given the breadth of activities happening simultaneously! Thank you for sharing the fact base information, this was useful to review what was captured from the interviews.

We learned of an interagency WG meeting led by USG therapeutics that took place this past Monday focused on doing a collective review of agents currently being tested and identifying any gaps with the prioritization process. Is this group one of the three lessons learned WG's discussed with the LT that will be led by ACTIV/NIH to review and develop actions for research, scoping, and prioritization (if so I would like to join and listen-in on those) or is this something else?

Thank you,
Ashley

From: Bugin, Kevin <b6>
Sent: Saturday, February 20, 2021 8:36 AM
To: Woodcock, Janet (FDA/OC) <b6>; Marks, Gilbert (OS/ASPR/BARDA) (CTR) <b6>; Parker, Ashley (NIH/OD) [E] <b6>; Adam, Stacey (FNIH) [T] <b6>; Armstrong, Kimberly (OS/ASPR/BARDA) <b6>

Cc: King, Mason [b6]; Ramakrishnan, Raahul [b6]
USARMY DOD JPEO CBRND (USA)' [b6]

Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Good morning Tx Lessons Learned Leadership Group,

Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: (b) (5) ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6]

Sent: Wednesday, February 10, 2021 1:51 PM

To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)

Cc: King, Mason; Ramakrishnan, Raahul; [b6] USARMY DOD JPEO CBRND (USA)'

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

-- Do not delete or change any of the following text. --

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Sent: 6/12/2020 6:41:19 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]
Subject: URGENT: serious issue for ACTIV therapeutics
Attachments: The scope of the OWS therapeutic team focus is further defined as.docx

Houston, we have a problem.

In the OWS Board meeting at 5 PM, Moncef spent most of the time talking about vaccines. (b) (5)
(b) (5)

Then in the last 15 minutes he got into therapeutics. (b) (5)
(b) (5)

(b) (5)

It was really uncomfortable. Ultimately the decision was that Moncef and I needed to work this out separately. As you can see, he is proposing to meet tomorrow. The times he is proposing won't work for me, so I plan to ask him for a call on Saturday. But I'll need to be prepared for that.

So I'll need answers to the following questions:

- 1) For the immunomodulators

From: moncef slaoui < > b6
Sent: Thursday, May 28, 2020 9:07 PM
To: Collins, Francis (NIH/OD) [E] < > b6
Subject: Re: Hoping to follow up soon

Dear Francis

Thank you for your note

(b) (5)

It is important to be clear that they need to have skin in the game rather than a free try .

I look forward to a good to a good scientific discussion Francis. As for all other areas my aim is to help support and speed availability of medicines and vaccines for patients.

I can talk tomorrow between 10:30 and 12 or 1:30 and 3pm

I hope one of these can work

Please let me know

With my best regards

Moncef

On May 28, 2020, at 8:47 PM, Collins, Francis (NIH/OD) [E] < b6 wrote:

Hi Moncef,

(b) (5)

. I need to pull all of the details together to give you a full briefing. Might we be able to talk tomorrow sometime? Or this weekend?

Many thanks for all the amazing progress you have made in less than two weeks!

Best, Francis

Sent: 6/3/2020 9:16:47 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: ACTIV immunomodulators -- responses to request for further information

See below. (b) (5)

From: moncef slaoui < > b6
Sent: Wednesday, June 3, 2020 5:05 AM
To: Collins, Francis (NIH/OD) [E] < > b6
Cc: Woodcock, Janet (FDA/CDER) < > b6 Wholley, David (FNIH) [T] < > b6
Adam, Stacey (FNIH) [T] < > b6 Fauci, Anthony (NIH/NIAID) [E] < > b6 Lane, Cliff (NIH/NIAID) [E] < > b6
Subject: Re: ACTIV immunomodulators -- responses to request for further information

Dear Francis

Thank you and the team for sharing this clear and extensive summary of the work and rational the ACTIV group did to prioritize the three anti inflammatory medicines for use in the Phase 2-3 ACTIV1 trial protocol.

Please note :

(b) (5)
(b) (5)

I have reviewed the document with interest and have the following feedback

1- Infliximab: (b) (5)
(b) (5)

2- Abatacept: (b) (5)
(b) (5)

3- Cenicriviroc: (b) (5)
(b) (5)

In summary , pending Janet's comments, I would support progressing with the ACTIV1 trial (b) (5)

Happy to discuss

COLL0000009637

With best regards

Moncef

On Jun 2, 2020, at 9:35 PM, Collins, Francis (NIH/OD) [E] [b6] > wrote:

Hi Moncef,

Following up our discussion last Saturday, I asked David Wholley and Stacey Adam of the Foundation for NIH (who serve as highly capable ACTIV program managers) to put together more detailed information about how the ACTIV therapeutic prioritization process has functioned. The attached document outlines that process in a series of ten steps. This prioritization process has been conducted by members of the ACTIV Clinical Therapeutics Working Group, co-chaired by Eric Hughes (Novartis) and Sarah Read (NIAID).

The document also provides additional background on the three therapeutic agents that were assigned the highest priority. The company producing each of these has indicated enthusiasm for participation, and assured ACTIV leadership that there would not be a problem in scaling up production, should a trial prove positive.

The ACTIV team and its Executive Committee endorsed the immediate testing of these three immunomodulators for hospitalized COVID-19 patients. The urgency of the effort to save lives of the sickest COVID-19 patients was considered sufficient reason to go directly to a Phase III trial (but with aggressive stopping rules for safety and futility), rather than a more traditional Phase II approach. As we discussed last Saturday, therefore, we seek approval to initiate the trial as soon as possible, at an

(b) (5)

Please let me, David, and Stacey know if you need additional information.

Best regards, Francis

<ACTIV Therapeutics Prioritization_060220.docx>

Sent: 6/3/2020 11:51:41 PM
To: moncef slaoui [REDACTED] b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
Subject: FW: ACTIV immunomodulators -- responses to request for further information
Attachments: annrheumdis-2020-217871.full.pdf; annrheumdis-2020-217871-inline-supplementary-material-1.pdf

Dear Moncef,

I asked David Wholley and Stacey Adam to address the questions you posed this morning about [REDACTED] (b) (5) See responses below in blue type.

The ACTIV Therapeutics Clinical Working Group certainly agrees that [REDACTED] (b) (5)
[REDACTED] (b) (5)

From: moncef slaoui [REDACTED] b6
Sent: Wednesday, June 3, 2020 5:05 AM
Subject: Re: ACTIV immunomodulators -- responses to request for further information

Dear Francis
Thank you and the team for sharing this clear and extensive summary of the work and rational the ACTIV group did to prioritize the three anti inflammatory medicines for use in the Phase 2-3 ACTIV1 trial protocol.
Please note : [REDACTED] (b) (5)
[REDACTED] (b) (5)

I have reviewed the document with interest and have the following feedback

- 1- Infliximab: [REDACTED] (b) (5)
[REDACTED] (b) (5)
[REDACTED] (b) (5)

- 2- Abatacept: [REDACTED] (b) (5)
[REDACTED] (b) (5)
[REDACTED] (b) (5)

(b) (5)

3- Cenicriviroc:

(b) (5)

(b) (5)

(b) (5)

In summary , pending Janet's comments, I would support progressing with the ACTIV1 trial (b) (5)

Happy to discuss

With best regards

Moncef

On Jun 2, 2020, at 9:35 PM, Collins, Francis (NIH/OD) [E] b6 > wrote:

Hi Moncef,

Following up our discussion last Saturday, I asked David Wholley and Stacey Adam of the Foundation for NIH (who serve as highly capable ACTIV program managers) to put together more detailed information about how the ACTIV therapeutic prioritization process has functioned. The attached document outlines that process in a series of ten steps. This prioritization process has been conducted by members of the ACTIV Clinical Therapeutics Working Group, co-chaired by Eric Hughes (Novartis) and Sarah Read (NIAID).

The document also provides additional background on the three therapeutic agents that were assigned the highest priority. The company producing each of these has indicated enthusiasm for participation, and assured ACTIV leadership that there would not be a problem in scaling up production, should a trial prove positive.

The ACTIV team and its Executive Committee endorsed the immediate testing of these three immunomodulators for hospitalized COVID-19 patients. The urgency of the effort to save lives of the sickest COVID-19 patients was considered sufficient reason to go directly to a Phase III trial (but with aggressive stopping rules for safety and futility), rather than a more traditional Phase II approach. As we

COLL0000009656

discussed last Saturday, therefore, we seek approval to initiate the trial as soon as possible, at an

(b) (5)

Please let me, David, and Stacey know if you need additional information.

Best regards, Francis

<ACTIV Therapeutics Prioritization_060220.docx>

Sent: 6/8/2020 11:49:26 PM
To: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]
Subject: FW: Following up

Hey there Janet,

I'm thinking we should get a response back to Moncef about these last questions on the immunomodulators. The ACTIV team looked at the items listed on p. 22 of last Thursday's handout, and said

From: Slaoui, Moncef <[REDACTED] b6 [REDACTED]>
Sent: Friday, June 5, 2020 3:36 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: moncef slaoui <[REDACTED] b6 [REDACTED]> Woodcock, Janet (FDA/CDER) <[REDACTED] b6 [REDACTED]>
Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>
Subject: Re: Following up

Hi Francis

Thank you for following up

I really only wanted to discuss how the funding may work [REDACTED] (b) (5)
[REDACTED] (b) (5)

Once these points are clarified and we have clarified the question [REDACTED] (b) (5) was insisting on, then we are good to go.
[REDACTED] (b) (5)

I will review the ACTIV leadership group deck over the week end and get back to you

With my best regards

Moncef

Tel: [REDACTED] b6 [REDACTED]

On Jun 4, 2020, at 11:14 PM, Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED] > wrote:

Hi Moncef,

That was an excellent presentation at OWS – you and Janet have done a tremendous amount of work to pull this all together.

I note that you indicated to the Board a plan to make a decision about the immunomodulators by next Friday. I stand ready to provide any other information that might help with this. The protocol (ACTIV-1) is 90% done, and the [REDACTED] (b) (4), (b) (5) [REDACTED] to get started on infliximab. [REDACTED] (b) (5) [REDACTED] (b) (5) cenicriviroc and abatacept, [REDACTED] (b) (5) [REDACTED] (b) (5) [REDACTED] (b) (5) Janet and I will check out the projects

that (b) (5), but I very much doubt if any of these are in a position to be adopted by ACTIV-1.

I also thought you might be interested in the slide deck from the ACTIV Leadership Group meeting from yesterday, so I have attached that. It was an excellent meeting with a lot of engagement and vigorous discussion from the ~65 participants. I'd be glad to answer questions about any parts of this. In fact, if you had time, David Wholley and I would welcome the chance to walk you through the materials. Just let me know.

Best, Francis

<ACTIV Leadership Team Meeting 20200603 FINAL.pptx>

Sent: 6/19/2020 6:37:24 AM
To: moncef slaoui [(b)6] Slaoui, Moncef (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94d0071e06c4440fa53795c867d9d858-Moncef.Slao]
CC: Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Following up
Attachments: ACTIV Leadership Team Meeting 20200603 FINAL.pptx

Hi Moncef,

That was an excellent presentation at OWS – you and Janet have done a tremendous amount of work to pull this all together.

I note that you indicated to the Board a plan to make a decision about the immunomodulators by next Friday. I stand ready to provide any other information that might help with this. The protocol (ACTIV-1) is 90% done, and the (b) (5), (b) (4) (b) (5), (b) (4) to get started on infliximab. (b) (5) cenicriviroc and abatacept, (b) (5) Janet and I will check out the projects that (b) (5), but I very much doubt if any of these are in a position to be adopted by ACTIV-1.

I also thought you might be interested in the slide deck from the ACTIV Leadership Group meeting from yesterday, so I have attached that. It was an excellent meeting with a lot of engagement and vigorous discussion from the ~65 participants. I'd be glad to answer questions about any parts of this. In fact, if you had time, David Wholley and I would really like the chance to walk you through the materials. Just let me know.

Best, Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E998E83770CFC7EE770-TABAKL]
Sent: 8/31/2020 3:07:09 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: FW: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners
Attachments: OWS - Connecting the Trials.pptx; Rise Above COVID Branding POV 8.17.20 FINAL.pdf

Flag: Follow up

fyi

From: "Bugin, Kevin" <[REDACTED]> b6
Date: Monday, August 31, 2020 at 11:06 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]> b6 "Wholley, David (FNIH) [T]" <[REDACTED]> b6
Cc: Janet Woodcock <[REDACTED]> b6 "Erhardt, William (HHS/IOS)" <[REDACTED]> b6
Subject: FW: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

Larry, David,
Please see attached for a couple of work in progress documents that describe the Rise Above COVID effort that Janet mentioned. We can discuss further when we meet. Thanks,

Kevin

From: Woodcock, Janet [REDACTED] b6
Sent: Monday, August 31, 2020 9:18 AM
To: Tabak, Lawrence A (NIH) <[REDACTED]> b6 Billet, Courtney R (NIH) [REDACTED] b6 Burklow, John T (NIH) [REDACTED] b6; Myles, Renate H (NIH) [REDACTED] b6 >; Johnson, Lenora E (NIH) [REDACTED] b6; Schmitt, Clare K (NIH) [REDACTED] b6 >; Bugin, Kevin <[REDACTED]> b6
Cc: Austin, Christopher P (NIH) [REDACTED] b6 >; Gibbons, Gary H (NIH) <[REDACTED]> b6 Lane, Henry C (NIH) [REDACTED] b6 >; Patterson, Amy (NIH) [REDACTED] b6; Perez-Stable, Eliseo J (NIH) [REDACTED] b6 [REDACTED] b6 Burrus-Shaw, Cyndi R (NIH) [REDACTED] b6; McManus, Ayanna L (NIH) [REDACTED] b6; Simon, Dina M (NIH) [REDACTED] b6 >; Wood, Gretchen S (NIH) [REDACTED] b6
Subject: RE: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

We at OWS are also seeing a proposal for "Rise Above COVID" that would be pan-trials. Need to make sure we merge these efforts and don't trip over each other. jw

From: Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6
Sent: Monday, August 31, 2020 8:46 AM
To: Woodcock, Janet [REDACTED] b6; Billet, Courtney R (NIH) [REDACTED] b6 >; Burklow, John T (NIH) [REDACTED] b6 >; Myles, Renate H (NIH) <[REDACTED]> b6 >; Johnson, Lenora E (NIH) [REDACTED] b6; Schmitt, Clare K (NIH) [REDACTED] b6 >
Cc: Austin, Christopher P (NIH) [REDACTED] b6; Gibbons, Gary H (NIH) <[REDACTED]> b6 Lane, Henry C (NIH) [REDACTED] b6; Patterson, Amy (NIH) [REDACTED] b6; Perez-Stable, Eliseo J (NIH) [REDACTED] b6; Burrus-Shaw, Cyndi R (NIH) [REDACTED] b6; McManus, Ayanna L (NIH) [REDACTED] b6; Simon, Dina M (NIH) [REDACTED] b6 >; Wood, Gretchen S (NIH) [REDACTED] b6

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< b6

Subject: Urgent: Need to meet re. General campaign to encourage individuals to become our research partners

Importance: High

Colleagues,

Francis hopes to meet with you (or your designee) today (or tomorrow at the latest) to discuss approaches for a general "campaign" to encourage people to become our research partners in the many Covid-19 trials. This needs to be done quickly and in a way that does not compete one trial versus another.

I would appreciate any flexibility you may offer in your schedule to allow us to meet today or tomorrow. If I have left off key communication staff members, please include them in the meeting invite.

Best wishes,
Larry

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Sent: 5/29/2020 4:15:52 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Hi Stacey,

We can hold off on placing the randomization figure in the slide to avoid any confusion and update if we have a diagram before noon on Monday.

Thank again and have a good night!
Ashley

From: Adam, Stacey (FNIH) [T] <[REDACTED] b6>
Sent: Friday, May 29, 2020 12:10 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6> Wholley, David (FNIH) [T] <[REDACTED] b6>
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Hi Ashley,

Yes, comment can be deleted.

[REDACTED] (b) (5)
[REDACTED] (b) (5) might be slightly different, I think it is fine.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>
Sent: Friday, May 29, 2020 12:05 AM
To: Adam, Stacey (FNIH) [T] <[REDACTED] b6> Wholley, David (FNIH) [T] <[REDACTED] b6>
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

I've made some additional minor edits. OK to include randomization scheme for slide 10? Please see attached.

Also, I plan to delete the comment in the 2nd bullet on this slide – assume this is worked out.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, May 28, 2020 11:10 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6> Adam, Stacey (FNIH) [T] <[REDACTED] b6>
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Got it – thank you both.

Ashley

From: Wholley, David (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, May 28, 2020 9:11 PM
To: Adam, Stacey (FNIH) [T] <[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Same as the one I just sent.

From: Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Sent: Thursday, May 28, 2020 9:03 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Hi Ashley,

Sorry for the multiple emails, the large file is delaying the exchange.

Please use this version edited by both David and I for FC.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [REDACTED] b6 | Mobile: [REDACTED] b6

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Thursday, May 28, 2020 8:55 PM
To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Adam, Stacey (FNIH) [T] <[REDACTED]> b6
Subject: Re: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Hi David and Stacey,

Checking to see if you or Stacey had edits to the slides before I send to Francis for review tonight. I'm thinking we should [REDACTED] (b) (5) — unless we'll have information before Monday morning.

Also, there was back and forth on the stats — [REDACTED] (b) (5) I may have heard a different approach today.

Thoughts?

Thanks,
Ashley

Begin forwarded message:

From: "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6>
To: "Wholley, David (FNIH) [T]" <[REDACTED] b6>
Subject: Re: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Just making sure you saw this. Hever has asked for final materials by tomorrow preferably – need to send to FC for review after your team.

Thanks!
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, May 28, 2020 1:20 AM
To: Wholley, David (FNIH) [T] <[REDACTED] b6> Adam, Stacey (FNIH) [T] <[REDACTED] b6>
Subject: RE: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Hi David and Stacey,

Attached is a draft set of slides for the 15-min ACTIV update with the Hever group. I've rearranged the order a bit and placed the Tx clinical updates at the end of the presentation to avoid jumping around and transition directly to the mAb trials requested by the group. Happy to reorder if preferred but need to pass by your team before sending to FC for review later today – Hever has asked for slides preferably by COB Friday, no later than noon Monday.

On the mAb slides – [REDACTED] (b) (5)
[REDACTED] Dolsten also asked about options for [REDACTED] (b) (5) – defer to your team if this should be depicted/included on the slides.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, May 25, 2020 2:01 PM
To: Wholley, David (FNIH) [T] <[REDACTED] b6> Parker, Ashley (NIH/OD) [E] <[REDACTED] b6>
Subject: FW: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

See instructions below from Sogaard about the coming Hever meeting. All this seems a bit over the top in prescribing the format, but ok.

With just 15 minutes for the ACTIV presentation, I would think we should use 5 or 6 slides about the overall status of the effort, and then a final slide or two on the mAb trials (since that is the request for focus). It would be great to have help from you two for that.

For the pre-read, I would think the JAMA article would be just fine. If you agree, I can send that to Morten now.

FC

From: b6 b6
Sent: Monday, May 25, 2020 12:58 PM
To: b6 Collins, Francis (NIH/OD) [E] <b6 Woodcock, Janet (FDA/CDER) <b6 Stoffels, Paul [JJCUS] b6 Plump, Andrew <b6
Cc: b6 b6 jill <b6 FMedSci Trevor <b6 b6 b6
Subject: June 2 HEVER COVID-19 call - Slide logistics and guidance for speakers

Dear All,

As we are getting closer to our June 2 HEVER COVID-19 meeting we are working to shore up the logistics for the meeting.

To that end we would like to ask you to

- Indicate if you plan to circulate pre-reads – if you are could you kindly submit them by Thursday May 28th End of Day EDT – so we can collate and send them out to the full team.
- Submit presentation slides by Monday June 1 by noon EDT at the latest – so we can collate into a master deck for efficient running of the meeting on June 2.

As you know we are working to set up a 30 min check-in meeting end of next week for presenters. Awaiting scheduling of this and realizing that it may be challenging to get on all calendars – we wanted to provide some guide lines (but ultimately your call)

- The meeting is scheduled to be 105 min but we are hoping that we might end at 90 minutes if we are disciplined.
- For the presentation we would recommend a few set up slides leading to one discussion slides outlining on the key proposals for the HEVER+ group to align on, and more detailed information in the pre-read.

Kindly submit slides to Morten Sogaard and Jill Payne cc to b6 and Trevor Jones

Best regards,
b6 on behalf of the team

Agenda for Hever Group video WebEx on 2nd June ~ 90 min discussion (planned for 105 min, but hoping to end early)

- Setting the stage b6) 5 min
- Update on coordination of US COVID Initiatives (Moncef Slaoui) 10 min
- Update on Covid R&D consortium ...pre-circulated **Clinical Trial Acceleration Overview** Update (Andy Plump)...Update on ACTIV trials with focus on new mAb master protocol (Francis Collins tbc) 30 min (15- + 15)
- **Regulatory streamlining** of COVID-19 Clinical Trials (Janet Woodcock w/ commentaries from key regulatory colleagues) 20 min
- **Data sharing** ... review and suggestions for the way forward (Andy Plump) and **Accumulus overview** incl. alignment w/ data repository landscape (Paul Stoffels) 40 min (20 + 20)

Sent: 4/23/2020 2:57:19 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: RE: Preparation for HEVER COVID-19 call
Attachments: HEVER_ACTIV_042420.pptx

Thanks, Francis. Gretchen – will you send the

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, April 22, 2020 9:47 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 George, Jill (NIH/OD) [E] <[REDACTED]> b6
Wholley, David (FNIH) [T] <[REDACTED]> b6 Wood, Gretchen (NIH/OD) [E] <[REDACTED]> b6 McManus, Ayanna (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: Preparation for HEVER COVID-19 call

Hi Ashley,

Thanks to you and Jill for putting this draft together. I did a little tinkering and ended up with something halfway between the short and the long version. The slides after the black one are back ups.

Can this set be submitted to Hever tomorrow, for presentation early Friday?

Tx, Francis

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Sent: Wednesday, April 22, 2020 6:33 PM
To: Collins, Francis (NIH/OD) [E] <col> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6
Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 George, Jill (NIH/OD) [E] <[REDACTED]> b6
Subject: RE: Preparation for HEVER COVID-19 call

Hi Francis,

With many thanks to Jill for converting these – please see attached slides for the HEVER COVID-19 meeting tomorrow.

I've attached 2 versions for your consideration. The email below from Morten explains you have 15 minutes followed by Q&A – please see 1st attachment with 14 slides. If you plan to present in 7-8 mins – please see 2nd attachment with 9 slides.

Additional slides are included in the back pocket.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Wednesday, April 22, 2020 2:20 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T] <[REDACTED]> b6

Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 George, Jill (NIH/OD) [E] <[REDACTED]> b6

Subject: RE: Preparation for HEVER COVID-19 call

Yes – Jill and I are already working on moving your slides into your background and we will work on trimming/reformatting the slides.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6

Sent: Wednesday, April 22, 2020 2:17 PM

To: Wholley, David (FNIH) [T] <[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6

Cc: Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6 George, Jill (NIH/OD) [E] <[REDACTED]> b6

Subject: RE: Preparation for HEVER COVID-19 call

I think that should be fine. Ashley, can you take the first crack on picking out a set that I could present in 7 – 8 minutes? I'm looping in Jill George to put her on alert that we'll need her help on reformatting.

FC

From: Wholley, David (FNIH) [T] <[REDACTED]> b6

Sent: Wednesday, April 22, 2020 12:54 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6

Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E] <[REDACTED]> b6

Subject: RE: Preparation for HEVER COVID-19 call

So you are just going to select what you need out of today's call and have your staff put them in the NIH format? Just want to be clear.

From: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6

Sent: Wednesday, April 22, 2020 12:29 PM

To: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> b6

Cc: McManus, Ayanna (NIH/OD) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E]

<[REDACTED]> b6 Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6 Wholley, David (FNIH) [T]

<[REDACTED]> b6

Subject: RE: Preparation for HEVER COVID-19 call

Yes, I will use slides, but they won't be ready until tomorrow.

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED]> b6

Sent: Wednesday, April 22, 2020 12:01 PM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6

Cc: McManus, Ayanna (NIH/OD) [E] <[REDACTED]> b6 Tabak, Lawrence (NIH/OD) [E]

<[REDACTED]> b6

Subject: Re: Preparation for HEVER COVID-19 call

Thanks, Francis. The HEVER team wants to know if you intend to use slides or have any background materials to share for that meeting. They would like them today, if possible.

From: Francis Collins <[REDACTED] b6 [REDACTED]>
Date: Wednesday, April 22, 2020 at 11:13 AM
To: Gretchen Wood <[REDACTED] b6 [REDACTED]>
Cc: "McManus, Ayanna (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: RE: Preparation for HEVER COVID-19 call

Yes, I am available and will have to skip the Response Team call on Friday.

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, April 22, 2020 9:57 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: McManus, Ayanna (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: FW: Preparation for HEVER COVID-19 call
Importance: High

Good morning, Francis,

Apologies for my confusion about this. Are you able to participate in this call starting at 7:30 AM on Friday? I thought I had seen another entry that had to do with a white paper last week. Appreciate your guidance.

From: [REDACTED] b6 [REDACTED] b6 [REDACTED]
Date: Tuesday, April 21, 2020 at 10:09 AM
To: Gretchen Wood <[REDACTED] b6 [REDACTED]> "McManus, Ayanna (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: FW: Preparation for HEVER COVID-19 call

Dear Gretchen/Ayanna,

I am following up on Morten's e-mail below regarding a HEVER COVID-19 meeting that is scheduled for Friday, April 24th at 7:30am EST. The meeting will take place with [REDACTED] b6 [REDACTED] b6 [REDACTED] from Pfizer and with about 25 other pharmaceutical leaders. Can you please confirm that Dr. Collins is indeed available at that time. I will send an invitation and dial-in instructions shortly.

Thank you and regards,
[REDACTED] b6 [REDACTED]

From: [REDACTED] b6 [REDACTED] b6 [REDACTED]
Sent: Monday, April 20, 2020 11:21 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Cc: b6 b6 b6 b6
b6 b6 b6 b6
< b6

Subject: Preparation for HEVER COVID-19 call

Dear Francis,

I hope all is well.

I am writing to follow up on your conversation with b6 about the upcoming HEVER COVID-19 meeting on Friday 7.30 a.m. EST.

The current thinking is that b6 will kick off the meeting to set the stage and that you would then give an overview of the ACTIV initiative - 15 minutes or so. This would be followed by a discussion with the broader group on actions that could be taken to align COVID-19 collaborative initiatives.

Andy Plump will be able to join for the first 30 minutes and is interested in contributing one or two slides on his initiative, which we could take either before your presentation or after.

We would like to ideally circulate slides by the end of Wednesday and were hoping that this might be acceptable, otherwise please let us know.

Because of the set up (WebEx) we would like to make sure that colleagues who have technical difficulties with the WebEx will be able to dial in and see the pre-circulated slides.

I cc b6 as well as b6 and Ann at our end for help with follow up.

Best Regards and Thank You, on behalf of b6 and myself,
b6

Sent: 5/5/2020 1:40:38 AM
To: b6 b6
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: ACTIV Executive Committee

Hi b6

Many thanks for all of your thoughtful input to ACTIV as we move this partnership forward at record speed. I am looking forward to hearing the working group reports on Wednesday.

A task that we haven't addressed yet is to make the Leadership Group a bit more organized. As you know better than almost anyone, for the Accelerating Medicines Partnership (AMP) projects we benefited from an Executive Committee, co-chaired by you and me, and populated with a few other senior members from both sectors. For ACTIV, Paul Stoffels has agreed to serve as co-chair with me, but I am hoping you might be willing to serve as an Executive Committee member. The duties will not be onerous -- FNIH staff will take care of all the logistics and planning, the main responsibility would be to look over draft agendas and help lead the Leadership Group discussions.

Let me know if you would be willing to do this – it would be great to have your expertise again, especially at this critical moment.

Best, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 8/3/2020 5:50:03 PM
Subject: *Call with Mikael Dolsten
Location: You will dial Mikael on [REDACTED] b6
Start: 8/5/2020 6:00:00 PM
End: 8/5/2020 6:30:00 PM
Show Time As: Busy

Recurrence: (none)

Hi Gretchen,

Mikael indicated that August 5 at 2 p.m. ET works well for him.

Will you issue an Outlook invite or shall I do so?

Mikael's mobile # is [REDACTED] b6

[REDACTED] b6

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6>
Sent: Monday, August 3, 2020 10:33 AM
To: [REDACTED] b6 [REDACTED] b6
Subject: Re: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Thanks very much!

From: [REDACTED] b6 <[REDACTED] b6>
Date: Monday, August 3, 2020 at 10:27 AM

COLL0000010076

To: Gretchen Wood <[REDACTED] b6>

Subject: RE: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Good morning, Gretchen.

I am checking with Mikael and will respond back to you as soon as I receive word from him.

Best regards,

[REDACTED] b6

From: Wood, Gretchen (NIH/OD) [E] <[REDACTED] b6>

Sent: Monday, August 3, 2020 7:15 AM

To: [REDACTED] b6 [REDACTED] b6

Subject: FW: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Good morning, Ann,

I hope that you had a nice weekend. Can we set up a 20-minute call this week for Francis and Mikael? We have the following available:

August 5 between 2:00 PM and 4:00 PM

August 7 at 9:15 AM or between 11:00 AM and 12:30 PM

Thanks very much!

Best wishes,

Gretchen

From: Francis Collins <[REDACTED] b6>

Date: Sunday, August 2, 2020 at 3:26 PM

To: Gretchen Wood <[REDACTED] b6> "McManus, Ayanna (NIH/OD) [E]" <[REDACTED] b6>

Subject: FW: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Can you find time for a 20 minute call with Dolsten this coming week?

Tx, FC

From: [REDACTED] b6 [REDACTED] b6
Sent: Saturday, August 1, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Subject: Re: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Francis

Thanks for the note .

I am fine to speak about our views in the matter raised by you below in a 1/1 call.

I will be on vacation in our summerhouse next week but have a flexible schedule for a call w you . Pls let me know when it's convenient for you .

By the way , amazing progress in AMP, feel so proud being part of this .

Enjoy the weekend
Best

[REDACTED] b6

Sent from my iPhone

On Aug 1, 2020, at 18:17, Collins, Francis (NIH/OD) [E] [REDACTED] b6 > wrote:

Thanks for your follow up note, [REDACTED] b6 l.

One more thought about DSMB chairs for the vaccine trials – could you be comfortable with their at least sharing data about safety signals? That would seem to be in public's best interest. I understand you don't want to see sharing of efficacy – but why not safety?

Best, Francis

From: [REDACTED] b6
Sent: Friday, July 31, 2020 2:13 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 >
Cc: [REDACTED] b6 ; Ledgerwood, Julie (NIH/NIAID) [E] [REDACTED] b6 >; [REDACTED] b6
[REDACTED] b6 < [REDACTED] b6 [REDACTED] b6
Subject: RE: Diversity in the Vaccine Clinical Trials

Dear Francis,

It was very nice speaking with you earlier this week. Our Chief Patient officer, Dara Richardson-Heron, who you know well, and our Head of Clinical Trial Experience, Judy Sowards, are reviewing the options you laid out below and will be reaching out to Jim and Julie directly to discuss.

I very much look forward to continuing this dialogue and exploring the ways we can work together to help ensure people from all demographics, who may have interest in participating in COVID-19 clinical trials are aware of, educated about and have access to them.

Sincerely,

b6

From: Collins, Francis (NIH/OD) [E] b6

Sent: Wednesday, July 29, 2020 8:36 AM

To: b6 < b6

Cc: Wood, Gretchen (NIH/OD) [E] < b6 McManus, Ayanna (NIH/OD) [E] < b6

Subject: RE: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Yes, let's get on a call to discuss. Gretchen and/or Ayanna can help find a good time.

Best, Francis

From: b6 b6

Sent: Monday, July 27, 2020 3:20 PM

To: Collins, Francis (NIH/OD) [E] b6 >

Cc: Lane, Cliff (NIH/NIAID) [E] b6 Fauci, Anthony (NIH/NIAID) [E] b6 >; Wholley, David (FNIH) [T] < b6 Tabak, Lawrence (NIH/OD) [E] < b6

Subject: Re: [EXTERNAL] RE: Diversity in the Vaccine Clinical Trials

Hi Francis

Thanks for the response .

We appreciate the opportunity to access the NIH data bases and I will have someone reaching out to your contact persons below .

For some of the general best practice aspects of special populations and diversity inclusions , maybe the ACTIV NIH Vaccine and Clinical sub-groups can serve as useful venues as we are participating in those .

I am fine to discuss additional aspects you brought up , such as DSMB processes in a 1:1 phone call with you

Best

b6

Sent from my iPhone

COLL0000010076

On Jul 26, 2020, at 20:53, Collins, Francis (NIH/OD) [E] <[REDACTED]> wrote:

Hi [REDACTED]

Thanks for your note, and my sincere apologies for the slow response. I've consulted with the folks who have set up the www.coronavirusepreventionnetwork.org in order to register those interested in vaccine trials. There is a general sense that [REDACTED] (b) (4)

(b) (4)

To come back to your original question, NIAID is happy to discuss ways of [REDACTED] (b) (4) Points of contact would be Jim Kublin [REDACTED] b6) and Julie Ledgerwood [REDACTED] b6).

Best, Francis

From: b [REDACTED] b6

Sent: Thursday, July 23, 2020 8:57 AM

To: Collins, Francis (NIH/OD) [E] <[REDACTED]> b6

Subject: Diversity in the Vaccine Clinical Trials

Dear Francis,

I hope this note finds you and your family well. I'm writing to ask your assistance in ensuring people who want to participate in COVID-19 clinical trials are able to easily access the information they need, and in efforts to support diversity in the vaccine clinical trials.

We know that speed in the recruitment of diverse clinical trial participants will be critical to moving *all* COVID-19 vaccine programs forward. I know you are keenly aware that educating the public about clinical trials, and making it as simple as possible to find a trial and participate, is essential to doing that.

In the quest for a vaccine for COVID-19, we are all in it together. In that spirit of partnership and collaboration, I respectfully request you consider including Pfizer's Covid-19 clinical trial, and the clinical trials of other non-U.S. government-sponsored COVID-19 studies, in the Covid-19 Prevention Network (CoVPN) registry.

Pfizer and other COVID-19 vaccine developers need help to ensure that participants in our trials reflect the disproportionate rates of infection in black and brown communities. Many NIH programs are rich resources and potential recruitment partners to reach diverse individuals who have already expressed an interest in research, including NCATS, CTSAs and the All of Us Research Program. If Pfizer and other study teams have the opportunity to benefit from access to these groups, this may help us to significantly diversify the participants in COVID-19 vaccine studies. Of course, we would be willing to provide any required information to ensure the success of these partnerships.

COLL0000010076

As the leader of the nation's medical research agency, we look to you for guidance on the advancement of all efforts to discover and develop vaccines to combat the virus that continues to take many lives in the U.S. and around the world. Thank you for your consideration, and I hope to hear from you soon.

Sincerely,

b6



Sent: 1/14/2021 2:04:11 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: URGENT: Need for slides for Hever Covid Teleconference 6 19th January 2021
Attachments: Hever videoconference January 19th 2021 Final.docx

Hi David,

I have been remiss in not reaching out sooner about this request for slides for the Hever meeting on January 19. Morten wants these by tomorrow (yikes!).

From: Sogaard, Morten <[REDACTED]> b6
Sent: Thursday, January 14, 2021 7:59 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]> b6
Cc: Jill Payne <[REDACTED]> b6 Collins, Francis (NIH/OD) [E] <[REDACTED]> b6 Sogaard, Morten <[REDACTED]> b6
Subject: RE: Hever Covid Teleconference 6 19th January 2021

Dear Ashley,

I hope all is well !

Just checking in on when we can expect the slides for Francis' two presentations for next Tuesday's HEVER meeting (Ideally in ppt format) as well as any pertinent pre-read information.

- 2.2 NIH/ACTIV Francis Collins 15 min (11.55 – 12.10 pm)
- 3.1 AMP Common Metabolic Diseases (T2D 2.0) programme Francis Collins (12.25 – 12.40 pm)

We were hoping that we could have all the slides collected for circulation by tomorrow Friday.

Thank you for your help and best regards,
Morten

From: Jill Payne <[REDACTED]> b6
Sent: Tuesday, January 12, 2021 12:14 PM
To: Jill Payne <[REDACTED]> b6
Cc: Sogaard, Morten <[REDACTED]> b6
Subject: [EXTERNAL] Hever Covid Teleconference 6 19th January 2021

Please find attached the latest agenda for the call on the 19th January.

It would be extremely helpful to have your presentations by Friday noon (Eastern time), so that they can be distributed to the Hever members as pre-reads with plenty of time for them to read through them.

Please send to me and also to Morten Sogaard who is copied above.

Many thanks for your assistance.

COLL0000010598

Kind regards

Jill Payne
On behalf of Hever

Email: [REDACTED] b6
Cell: [REDACTED] b6

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